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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MSP RECOVERY CLAIMS, SERIES LLC; MSPA CLAIMS 1, LLC; MAO-MSO RECOVERY II, LLC, SERIES PMPI, a segregated series of MAO-MSO RECOVERY II, LLC; MSP RECOVERY CLAIMS SERIES 44, LLC; MSP RECOVERY CLAIMS PROV, SERIES LLC, and MSP RECOVERY CLAIMS CAID, SERIES LLC, PLAINTIFFS, v. CELGENE CORPORATION, BRISTOL-MYERS SQUIBB COMPANY, CHRONIC DISEASE FUND d/b/a GOOD DAYS FUND, and PATIENT ACCESS NETWORK FOUNDATION, DEFENDANTS.	Civil Action No.: 2:21-cv-20451-ES-JBC **SECOND AMENDED CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

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Plaintiffs, MSP Recovery Claims, Series LLC; MSPA Claims 1, LLC; MAO-MSO Recovery II, LLC, Series PMPI, a segregated series of MAO-MSO Recovery II, LLC; MSP Recovery Claims Series 44, LLC; MSP Recovery Claims PROV, Series LLC; and MSP Recovery Claims CAID, Series LLC (collectively "Plaintiffs"), and (the "Class Members")[1] by and through counsel, Santomassimo Davis LLP, bring this Second Amended Complaint ("Amended Complaint"), against Defendants Celgene Corporation ("Celgene"), the Chronic Disease Fund, also known as the Good Days Fund ("CDF,"), and the Patient Access Network Foundation ("PANF") (collectively referred to as "Defendants") and state as follows:

NATURE OF THE ACTION

1. Plaintiffs bring this action for violations of federal and state statutes, arising out of Defendants' involvement in anticompetitive schemes, that (1) prevented generic brands from entering the market to compete with Celgene's high-priced drugs Thalomid and Revlimid, and (2) provided illegal kickbacks that reduced market sensitivity to price increases, thus increasing prescription volume by secretly subsidizing patient co-payment, co-insurance, or deductible (collectively, "co-pay") obligations for its drugs through 501(c)(3) charities.

As a result of this anticompetitive conduct, Celgene's revenue and profit increased dramatically. This illegal conduct enabled Celgene to maintain supra-competitive prices by stifling competition that would have benefited health plans, consumers, and the public at large. Defendants' misconduct is emblematic of the recent, unprecedented increases in pharmaceutical drug costs. Upon information and belief, Celgene utilized co-payment assistance 501(c)(3)

[1] The full class is defined below, Section XIV. The Class Members Consist of Medicare Advantage Health Plans —i.e., Medicare Advantage entities such as Medicare Advantage Organizations ("MAOs"), Independent Practice Associations ("IPAs"), Management Services Organizations ("MSOs"), Health Maintenance Organizations ("HMOs"), and other Medicare first-tier, downstream, and related entities — and their assignees (collectively referred to as "MA Plans" or "Medicare Advantage health plans").

charities, primarily CDF and PANF, to circumvent Congressionally mandated co-payment requirements for Medicare beneficiaries (referred to herein as "Co-Payment Circumvention Enterprise"). Co-payments by Medicare beneficiaries are intended to create price sensitivity among patients and discourage medically unnecessary drug therapies. As a result of Defendants eliminating the co-payment requirements for Medicare beneficiaries, Plaintiffs' assignors and other Class Members paid for prescriptions for Celgene's Thalomid and Revlimid drug therapies that otherwise would not have been made or would have been substituted for less expensive generic equivalents in violation of 18 U.S.C. § 1962(c) and (d).

2. In January of 2019, the House of Representatives, Committee on Oversight and Reform ("Congress") launched a sweeping investigation into pricing and business practices in the pharmaceutical industry.[2] In its three-year-long investigation, Congress identified certain pharmaceutical companies (including Celgene and Bristol Myers Squibb) that have engaged in anticompetitive and fraudulent conduct resulting in supra-competitive prices being charged to Medicare and Medicaid.

3. In September of 2020, Congress released a report (and supporting evidence) called *Drug Pricing Investigation: Celgene and Bristol Myers Squibb.* (Attached hereto as Exhibit A). After reviewing over a million pages of documents obtained by Defendants, Celgene and Bristol Myers Squibb (hereinafter collectively referred to as "Celgene"), the September 2020 Report revealed the anticompetitive and fraudulent conduct engaged in by Celgene to enable it to charge

[2] The investigation was initiated by former Chairman, the late Elijah E. Cummings, and was named *Investigation of Skyrocketing Prescription Drug Prices.* Congress has made all documents (including investigative reports and evidence in support of those reports), and hearings (including testimony from the CEOs of the major pharmaceutical companies) available on the House Committee on Oversight Reform website at https://oversight.house.gov/investigations/investigation-of-skyrocketing-prescription-drug-prices

supra-competitive prices to Medicare and Medicaid (hereinafter collectively referred to as the "Government" or "Medicare").

4. In December of 2021, Congress released a subsequent report (and supporting evidence) called *Drug Pricing Investigation: Majority Staff Report* where it further discussed the grossly anticompetitive and fraudulent conduct of 10 pharmaceutical companies – including Celgene. (Ex. B). The key findings of these reports are further identified below, following the introduction of the Parties in Section II.

5. For background purposes, Thalomid was originally developed, marketed, and sold under the brand name Thalidomide, in the late 1950s and early 1960s, as a sedative and anti-nausea medication. Thalidomide had catastrophic results, causing fetal deformation when taken by expectant mothers.[3] In 1998, Celgene obtained U.S. Food and Drug Administration ("FDA") approval to market Thalomid (thalidomide) for a leprosy complication known as erythema nodosum leprosum ("ENL").

6. In 2005, Celgene successfully developed a thalidomide analog, Revlimid (lenalidomide), and obtained FDA approval to market it for a specific chromosomal variant of myelodysplastic syndrome ("MDS"). Celgene would later obtain FDA approvals for additional Revlimid indications, including for a subset of multiple myeloma ("MM") patients in 2006,[4] and a subset of mantle cell lymphoma ("MCL") patients in 2013.

[3] Ann Dally, *Thalidomide: was the tragedy preventable?*, THE LANCET 1197-99 (Vol. 351, Apr. 18, 1998).

[4] Under the FDA's orphan drug exclusivity program, 21 U.S.C. §§ 360aa-cc, the FDA may not approve a generic equivalent for a specific indication or "rare disease" that a brand drug is FDA-approved to treat for a period of seven years. MM is such a "rare disease." Therefore, until May 25, 2013, the FDA could not approve a generic thalidomide for the treatment of MM. It could, nevertheless, approve generic thalidomide for the treatment of other indications. This is known as a "skinny label."

7. Unsatisfied with the profit realized from these products, Celgene chose to engage in an illegal, multi-prong, anticompetitive scheme. First, Celgene unlawfully maintained market exclusivity for these drugs by interfering with competitors' efforts to develop or obtain FDA approval for generic versions of Thalomid and Revlimid. Second, Celgene illegally funneled money through co-payment charities to subsidize the co-payments of Medicare beneficiaries, in violation of the federal anti-kickback statute, thus eliminating a major factor in price sensitivity for these patients.

8. In furtherance of its anticompetitive schemes, Celgene: (1) manipulated the safety program designed to protect patients from thalidomide and lenalidomide's teratogenic properties; (2) prevented pharmacies and ingredient suppliers from acting as alternative sources of samples for such would-be generic competitors; (3) fraudulently obtained various patents from the U.S. Patent and Trademark Office ("USPTO") for Thalomid and Revlimid and their associated safety distribution protocols; (4) filed a series of "sham" patent infringement lawsuits; (5) filed baseless citizen petitions with the FDA to stymie generic approvals.

9. In the rare instances where Celgene's efforts failed to prevent a would-be competitor from prosecuting an Abbreviated New Drug Application ("ANDA"), and FDA approval of an ANDA for a generic version of Revlimid or Thalomid became possible, Celgene entered into confidential settlements with its competitors that included anticompetitive "pay-for-delay" reverse payments. The federal government has routinely criticized—and challenged in court—the same anticompetitive practices that Celgene engaged in.[5]

[5] *See, e.g.*, Federal Trade Commission, *Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf (last accessed Feb. 17, 2022).

10. Celgene's anticompetitive conduct facilitated regular price increases for over ten years. For example, in 2006, a one-month supply of Revlimid cost $6,195.[6] In 2010, the price was about $8,000 for a one-month supply. Currently, a 28-day supply of Revlimid can cost up to $20,000, and a 28-day supply of Thalomid can cost up to $10,000. When Revlimid first entered the market in 2005, it cost approximately $215 per pill. As of September of 2020, Celgene had raised the price of Revlimid 22 times, increasing the price to $719 per pill.

11. When Thalomid first entered the market, it cost approximately $6 per capsule. In 2014, its price reached $357 per capsule. Celgene's illicit and monopolistic scheme with respect to Thalomid and Revlimid have been enormously profitable. Between 2007 and 2016, Celgene recorded $35.3 billion of Revlimid sales and $3.2 billion of Thalomid sales, broken down by year below (numbers are in millions):[7]

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
Revlimid	$774	$1,325	$1,706	$2,470	$3,208	$3,767	$4,280	$4,980	$5,801	$6,974
Thalomid	$447	$505	$437	$390	$339	$302	$245	$221	$185	$152
Totals:	$1,221	$1,830	$2,143	$2,860	$3,547	$4,069	$4,525	$5,201	$5,986	$7,126

12. In December 2016, Revlimid was the second-highest grossing drug worldwide.[8] In 2020, Celgene (i.e., Bristol-Myers Squibb) reported that Revlimid revenue had grown to more than $12.1 billion worldwide, including more than $8.29 billion in the United States.[9]

[6] Alison Kodjak, *How A Drugmaker Gamed The System to Keep Generic Competition Away* (May 17, 2018), https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[7] Net product sales figures drawn from Celgene's Annual Reports/Form 10-K filings for fiscal years ending 2007-2016. All numbers are in millions

[8] Amy Brown, *EP Vantage 2017 Preview* (Dec. 2016), http://info.evaluategroup.com/rs/607-YGS-364/images/EPV2017Prev.pdf.

[9] *Bristol Myers Squibb Reports Fourth Quarter and Full-Year Financial Results for 2020*, BRISTOL MYERS SQUIBB (Feb. 4, 2021) https://news.bms.com/news/details/2021/Bristol-Myers-Squibb-Reports-Fourth-Quarter-and-Full-Year-Financial-Results-for-2020/default.aspx.

13. As a result of Celgene's anticompetitive conduct, there has never been a generic competitor to Revlimid or Thalomid in the U.S.

14. Plaintiffs are assignees of recovery rights from health plans, including Health Maintenance Organizations ("HMO"), Medicare Advantage organizations ("MAO"), first-tier, downstream, and related Medicare entities, state Medicaid health care providers, and commercial health plans (collectively, the "Health Plans" or "Assignors"), all of which provide health care coverage and benefits, including prescription drug coverage, to plan beneficiaries ("Enrollees").

15. Plaintiffs seek to recover monetary damages as redress for over payments made on behalf of Assignors and other potential Class Members who purchased or otherwise provided reimbursement for overpriced or unnecessary Thalomid or Revlimid prescriptions that were paid for by the Assignors. Additionally, Plaintiffs seek treble damages, attorneys' fees, court costs, interest on all monetary damages, injunctive relief, and any such further relief this Court deems just and proper, under all the circumstances.

I. JURISDICTION AND VENUE

16. This Court has jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1337 as well as 15 U.S.C. §§ 15 and 26.

17. Plaintiffs assert claims for violation of federal statutes. As redress for the harms suffered, Plaintiffs seek treble damages (as prescribed under federal law), injunctive relief prohibiting Defendants from continuing to engage in anticompetitive market behaviors, court fees and other costs, including reasonable attorneys' fees, under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

18. This Court has supplemental jurisdiction over Plaintiffs' state law claims pursuant to 28 U.S.C. § 1367, as the state law claims are so intertwined with the federal claims and arise out of the same common nucleus of operative facts that they are necessarily part of the same case and controversy. Additionally, supplemental jurisdiction will avoid duplicative actions and

potentially conflicting outcomes, and thus should be exercised in the interests of judicial economy and fairness to all parties.

19. This Court has personal jurisdiction over Defendants because Defendants have intentionally conducted continuous and systematic business activities in the State of New Jersey and have substantial contacts in this state, such that Defendants can fairly be said to be at home in this state. *See generally Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). Plaintiffs' claims are properly adjudicated here, where many of Defendants' bad acts occurred.

20. Venue is appropriate within this District because Defendants transact business within this District, have agents and can be found in this District, and the cause of action or some part thereof arose in this District. Venue is also appropriate within this District under Section 12 of the Clayton Act, 15 U.S.C. § 22, and 28 U.S.C. §§ 1391(b) and (c).

II. PARTIES

21. Plaintiff, MSP Recovery Claims, Series LLC ("MSPRC"), is a Delaware limited liability company with its principal place of business located in Coral Gables, Florida.

22. MSPRC's limited liability company agreement provides for the establishment of one or more designated series. MSPRC has established various designated series pursuant to Delaware law in order to maintain various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

23. MSPRC has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to MSPRC. MSPRC may receive assignments in the name of MSPRC and further associate such

assignments with a particular series or may have claims assigned directly to a particular series. In either event, MSPRC and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. MSPRC retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of this Plaintiff the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, MSPRC, through its operating agreement, is authorized and empowered to obtain the relief sought herein. MSPRC's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

24. Plaintiff, MSPA Claims 1, LLC ("MSPA"), is a Florida limited liability company, with its principal place of business located in Coral Gables, Florida. One or more Health Plans irrevocably assigned to MSPA the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, MSPA is authorized and empowered to obtain the relief sought herein. MSPA's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

25. Plaintiff, MAO-MSO Recovery II, LLC, Series PMPI, a segregated series of MAO-MSO Recovery II, LLC ("MAO-MSO"), is a Delaware limited liability company with its principal place of business in Cresskill, New Jersey. One or more Health Plans irrevocably assigned to MAO-MSO the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, MAO-MSO is authorized and empowered to obtain the relief sought herein. MAO-MSO's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

26. Plaintiff, MSP Recovery Claims Series 44, LLC ("Series 44") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Series 44's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Series 44 established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and to account for and associate certain assets with certain particular series.

27. Series 44 has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Series 44. Series 44 may receive assignments in the name of Series 44 and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Series 44 and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Series 44 retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of this Plaintiff the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, Series 44, through its operating agreement, is authorized and empowered to obtain the relief sought herein. Series 44's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

28. Plaintiff, MSP Recovery Claims PROV, Series LLC ("Claims PROV") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims PROV's limited liability company operating

agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims PROV established various designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

29. Claims PROV has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims PROV. Claims PROV may receive assignments in the name of Claims PROV and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims PROV and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims PROV retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plans irrevocably assigned to certain series of Claims PROV the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, Claims PROV, through its operating agreement, is authorized and empowered to obtain the relief sought herein. Claims PROV's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

30. Plaintiff, MSP Recovery Claims CAID, Series LLC ("Claims CAID") is a duly organized and existing Delaware series limited liability company with its principal place of business located in Coral Gables, Florida. Claims CAID's limited liability company operating agreement provides for the establishment of one or more designated series as permitted by Delaware law. Del. Code Ann. Tit. 6, § 18-215(a). Accordingly, Claims CAID established various

designated series to serve as units of the company for the purpose of maintaining various claims recovery assignments separate from other company assets, and in order to account for and associate certain assets with certain particular series.

31. Claims CAID has enumerated rights relating to its designated series pursuant to its limited liability agreement and consistent with Delaware law. Del. Code Ann. Tit. 6, §§ 18-215(a)-(c). Specifically, all rights and benefits arising from assignments to its series shall belong to Claims CAID. Claims CAID may receive assignments in the name of Claims CAID and further associate such assignments with a particular series or may have claims assigned directly to a particular series. In either event, Claims CAID and the designated series are authorized to pursue or assert any claim or suit capable of being asserted by any designated series arising from, or by virtue of, an assignment to a designated series. Claims CAID retains the legal right to sue on behalf of each designated series and pursue all rights, benefits, and causes of action arising from assignments to a series in its own name or in the name of the designated series. One or more Health Plan irrevocably assigned to certain series of Claims CAID the right to assert the causes of action alleged in this Amended Complaint. As a result of said assignments, CAID, through its operating agreement, is authorized and empowered to obtain the relief sought herein. Claims CAID's assignments, samples of which are alleged in detail in the Appendix to this Amended Complaint, are valid and binding contracts.

32. Assignors provide health care benefits to their Enrollees, who reside throughout the United States. As third-party payers of pharmaceutical claims for their Enrollees, Assignors are "end-payers" for their Enrollees' Thalomid and Revlimid prescriptions and are thereby injured as a result of Celgene's unlawful behavior. Assignors' claims data confirms that, during the relevant time period, they purchased and/or reimbursed the cost for Thalomid and Revlimid throughout the United States. When generic versions of prescription drugs are available, Assignors and/or their Enrollees typically purchase, or reimburse the cost of, those generic versions. As Celgene has

effectively blocked the market entry of generic competitors, Assignors have purchased or reimbursed the cost of Thalomid and Revlimid at anticompetitive price levels throughout the United States. Here, Plaintiffs pursue damages related to those overpayments.

33. Defendant Celgene is a drug manufacturer, incorporated in Delaware and headquartered in Summit, New Jersey. Celgene manufactures, markets, and sells Thalomid and Revlimid. On November 20, 2019, Defendant Bristol-Myers Squibb Company announced the completion of its acquisition of Celgene, making Celgene a wholly owned subsidiary of Bristol-Myers Squibb.

34. Defendant CDF is a Texas non-profit corporation with a principal place of business in Frisco, Texas. CDF operates funds that receive donations from, *inter alia*, pharmaceutical manufacturers, and uses a portion of those payments to subsidize drug co-payment obligations of patients, including Assignors' Enrollees and the Class Members.

35. Defendant Bristol-Myers Squibb ("BMS") is incorporated in Delaware and has its principal place of Business in New York.

36. Defendant PANF, the Patient Access Network Foundation, is a 501(c)(3) organization located in Washington, D.C. PANF operates funds that receive donations from, *inter alia*, pharmaceutical manufacturers, and uses a portion of those payments to subsidize drug co-payment obligations of patients, including Assignors' Enrollees and the Class Members.

III. HOUSE COMMITTEE ON OVERSIGHT AND REFORM: *INVESTIGATION OF SKYROCKETING PRESCRIPTION DRUG PRICES*

37. In 2019, the Committee on Oversight and Reform ("Congress") "launched one of the most comprehensive and in-dept investigations of drug price increases that Congress has ever conducted." (**Ex. A** – September 2020 Report; **Ex. G –** *House Committee Initiates Sweeping Drug Price Investigation*).

38. On September 30, 2020, Congress released the following report titled *Drug Pricing Investigation: Celgene and Bristol Myers Squibb—Revlimid,* with the following key findings:

a. "**Uninhibited Price Increases:** Since launching Revlimid in 2005, Celgene raised the price of the drug 22 times, from $215 per pill to $719 per pill. After Bristol Myers Squibb obtained the rights to Revlimid last November, it raised the price of Revlimid again, to $763 per pill. Due to these price increases, a monthly course of Revlimid is priced at $16,023 today—more than triple the 2005 price." (**Ex. A**, p. i).

b. "**Corporate Profits Driven by Price Increases**: Due to Revlimid price increases, from 2009 to 2018, Celgene reported over $51 billion in net worldwide revenue from Revlimid, with the U.S. market accounting for $32 billion of that total. Celgene's net U.S. revenue for Revlimid increased from $1 billion in 2009 to nearly $6.5 billion in 2018. This rise in Revlimid revenue fueled Celgene's annual profits, which increased from $780 million in 2009 to $4 billion in 2018." (**Ex. A**, p. i).

c. "**Pricing Decisions Driven by Revenue and Earnings Goals**: Internal communications show that pricing decisions made by Celgene executives—including former CEO Mark Alles—were driven almost exclusively by the need to meet company revenue targets and shareholder earnings goals. In one instance, Mr. Alles orchestrated an emergency price increase for Revlimid in 2014 to ensure that Celgene met its quarterly revenue targets. To justify the price increase, Mr. Alles wrote, 'I have to consider every legitimate opportunity available to us to improve our Q1 performance.'" (**Ex. A**, p. i).

d. "**Executive Compensation System Incentivizes Price Increases**: Celgene's price increases for Revlimid led directly to higher bonuses for its executives. In 2016 and 2017, Celgene's top executives earned millions in additional bonuses because of their price increases for Revlimid." (**Ex. A**, p. i).

e. "**Targeting the U.S. for Higher Prices and Lack of Medicare Negotiation**: In internal documents, Celgene highlighted that the U.S. government is prohibited from negotiating directly to lower prices for Medicare beneficiaries. With the federal government unable to negotiate, Celgene targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world. One presentation described the U.S. as a 'highly favorable environment with free-market pricing.'" (**Ex. A**, p. I)[10]

[10] *See also,* **Ex. E,** *Critical Need for Legislation to Allow Federal Government to Negotiate Directly with Drug Companies*; **Ex. H,** *Office of Inspector General Report: Hight-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage*; **Ex. I,** *Top Dems Introduce Bill to Allow HHS to Negotiate Lower Drug Prices for Medicare;* **Ex. K**, *Schakowsky, Cummings, DeLauro, and Welch Introduce Comprehensive Bill to Address Drug Pricing;* **Ex. L**,

f. "**Cost to Taxpayers**: The federal government's inability to negotiate for a lower price of Revlimid has placed a significant burden on the U.S. health care system and cost taxpayers billions of dollars. From 2010 to 2018, Celgene collected $17.5 billion from Medicare Part D. In 2018 alone, Medicare Part D plans and beneficiaries spent more than $4 billion on Revlimid—the second-highest expenditure of any drug that year." (**Ex. A**, p. ii).

g. "**Anticompetitive Tactics to Maximize Profits**: Internal presentations show that Celgene suppressed competition by abusing a government-mandated safety program. Celgene emphasized that it could use the program for the 'prevention of generic encroachment.' Celgene also excluded competition by leveraging the U.S. patent system, which Celgene described internally as being far more protective of its monopoly pricing than patent systems in the rest of the world. Celgene's anticompetitive tactics are estimated to cost the U.S. health care system more than $45 billion through 2025." (**Ex. A**, p. ii).

h. "**Price Increases Not Justified by R&D Expenses**: Celgene relied heavily on taxpayer-funded academic research to develop Revlimid, and its internal pricing decisions appear to have been unrelated to past or future investment in research and development. Internal documents suggest that Celgene may have leveraged the high price of Revlimid to inhibit other companies' cancer research. In discussions about another company, one executive wrote, 'Making them spend a lot more on their trials puts financial constraints on their ability to simultaneously fund lots of trials.' Another executive agreed, writing, 'Anything we can do to hamper their development would help.'" (**Ex. A**, p. ii).

i. **Price Increases Not Justified by Rebates**: Celgene's internal data undermine the pharmaceutical industry's claims that price increases are the result of increased rebates, discounts, and other fees provided to pharmacy benefit managers. Celgene paid no negotiated discounts to Medicare Part D plans, and the largest discount it paid in the commercial market was only 5%. Celgene's average net price per unit of Revlimid—the price of the drug after removing such rebates, discounts, and fees—increased each year the drug has been on the market." (**Ex. A,** p. ii).

39. In December of 2021, after three years of investigating "some of the largest and most profitable drug companies in the world", and after reviewing of over 1.5 million pages of documents, Congress released a 269-page Report (*with supporting evidence)* identifying the

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Cummings and Welch Propose Medicare Drug Negotiation Bill in Meeting with President; **Ex. M,** *Affordable and Safe Prescription Drug Importation Act Introduced to Help Lower Skyrocketing Cost of Medicine;* **Ex. N,** *Sanders, Cummings Introduce Comprehensive Legislation to Lower Soaring Drug Prices*).

following key findings relating to Celgene's (and BMS's) anticompetitive and fraudulent conduct relating to its drug, Revlimid,

a. According to publicly available information at the time the investigation was launched, Celgene's drug, Revlimid, was among the costliest per Medicare beneficiary, resulted in the highest aggregate spending by the Medicare Part D program, or had the largest price increases." (**Ex. B**, p. iv).

b. Since launch Celgene has increased the price of Revlimid 20+ times. (**Ex. B**, p. vi).

c. Revlimid is 255% more expensive than it was at launch. (**Ex. B**, p. vi).

d. "Former Celgene CEO Mark Alles received more than $500,000 in bonus payments in 2016 and 2017 solely attributable to the company's price increases for the cancer drug Revlimid." (**Ex. B**, p. vii).

e. Celgene targeted the U.S. market for higher prices and used the Medicare program to boost revenue. (**Ex. B**, p. vii – viii).

f. Celgene abused the patent system and FDA regulations to suppress competition. (**Ex. B**, ix).

g. Celgene filed 109 patents, and blocked potential competition for 40 years. (**Ex. B**, p. ix).

h. Celgene used taxpayer money to fund the research for its drugs; therefore, Celgene's claim that the inflated prices of its drugs are related to research and development is pretextual. (**Ex. B**, p. xv, xvii).

i. As of December 2021, Revlimid was priced at more than $200,000 for a standard annual course of treatment and generated $6.27 billion in U.S. net revenue in 2019. (**Ex. B**, p. 4).

j. Without three price increases of Revlimid in 2017, "Celgene would not have accrued nearly $600 million in revenue—enough to prevent executives from collecting bonuses." (**Ex. B**, p. 13).

k. Celgene's pricing practices were "driven in large part by ambitious revenue goals." (**Ex. B**, p. 34.)

l. From 2016 to 2020, while Celgene continued to unjustifiably increase prices of Revlimid, the executives received $260,140,942 in compensation and bonuses. (**Ex. B**, p. 40).

m. From 2016 to 2020, while Celgene continued to unjustifiably increase prices of Revlimid, the CEO received $84,784,300. "The Committee's investigation identified company bonus structures that tie compensation to increasing drug-specific revenue targets year after year, creating incentives for executives to raise prices to meet those targets." (**Ex. B**, p. 42).

n. "Celgene also awarded senior executive bonuses through formulas based largely on revenue and earnings targets that increased by billions of dollars each year. Analysis of internal company data shows that, in several different years, Celgene's executives would not have met their bonus targets if not for their decision to increase the U.S. price for Revlimid. In 2017, two of Celgene's bonus incentive plans for executives, the Management Incentive Plan (MIP) and the Long-Term Incentive Plan (LTIP), set bonus net revenue targets of $13 to $13.4 billion and $12.8 billion, respectively. Celgene barely met these targets in 2017, collecting $13 billion in net revenue—$5.4 billion of which came from Revlimid, more than from any other drug.[]" (**Ex. B**, p. 43).

o. "Without three Revlimid price increases in 2017, Committee staff estimate that Celgene would not have accrued nearly $600 million in revenue—enough to prevent executives from collecting bonuses. [] For 2016 and 2017, Committee staff calculated that Revlimid price increases enabled executives to reach their bonus targets, accounting for more than $2 million in additional compensation for Celgene senior executives in those years." (**Ex. B**, p. 43)

p. Celgene's former Senior Vice President of Sales and Marketing, Frances Brown, testified that demand for Revlimid did not increase or decrease as a result of a price change.[11] (**Ex. B**, p. 44)

q. "Internal data produced by Celgene demonstrates that price increases on Revlimid were not attributable to increased rebates or discounts between 2009 and 2018. In fact, Celgene reported to the Committee that it paid no negotiated discounts to Medicare Part D plans, and its largest discount in the commercial market was only 5%. [] As a result, the average net price per unit of Revlimid increased annually, from $293.79 in 2009 to $598.21 in 2018…[C]ore to Celgene's pricing strategy was to achieve revenue growth by 'realiz[ing] favorable next price,' meaning to increase the price of Revlimid at a rate faster than any rebates or discounts paid to the supply chain." (**Ex. B**, p. 48-49)

r. "A 2018 Celgene multinational market analysis characterized the United States as a '[h]ighly favorable environment with free-market pricing.'" (**Ex. B**, p. 68).

s. "[A Celgene] presentation included one of the key strategies for Celgene to 'win': '[p]rotect free market competition-based pricing for Medicare and commercial insurance' in the United States. [] However, the presentation reflected a concern that

[11] (Citing *Mylan Pharmaceuticals Inc. v. Celgene Corporation*, No. 14-CV-02094 (D. N.J.) (Dec. 2, 2015).

future U.S. market dynamics may be less favorable to high prices given '[i]ncreased scrutiny on pricing practices' and '[g]reater expectation to demonstrate 'value'' of pharmaceutical products.'"[12] (**Ex. B**, p. 68)

t. "The Initiative for Medicine, Access, and Knowledge (I-MAK) estimates that Bristol Myers Squibb's patents on Revlimid will extend its monopoly until at least 2026 and will increase U.S. health care spending by $30 billion." (**Ex. B**, p. 80)

u. "While a limited-volume generic may enter the market in 2022 per Celgene's Settlement Agreements, unlimited generics may not enter the market until January 2026."[13] (**Ex. B**, p. 80)

v. "[O]ne Celgene presentation from 2014 estimated that Celgene had an 80% chance of maintaining its Revlimid monopoly in the United States until April 2025 and a 50% chance of maintaining its monopoly in the United States until April 2027. In comparison, the presentation estimated that Celgene's Revlimid monopoly would expire in the EU on or before March 2023—two years prior to the earliest estimated U.S. expiration." (**Ex. B**, p. 86).

w. "The Committee's investigation also found that Celgene (acquired by Bristol Myers Squibb in 2019) leveraged patent settlement agreements with at least six potential competitors to delay competition for its cancer drug Revlimid. Celgene's original patent on Revlimid's active ingredient expired in October 2019. As a result of the company's settlement agreements with competitors, however, a fully competitive generic market will not exist until at least 2026. These anticompetitive volume limitations leave consumers with artificially higher prices, while allowing Bristol Myers Squibb to maximize its profits far beyond the expiration of its original patent." (**Ex. B**, p. 95) "These agreements have significantly delayed U.S. patients' access to lower-priced drugs and cost the U.S. health care system billions of dollars in excess expenditures." (**Ex. B**, p. 91)

x. "Bristol Myers Squibb delayed lower-priced biosimilar and generic drugs in the United States by entering into settlement agreements with potential competitors that challenged their patents." (**Ex. B**, p. 78)

y. "In 2022—three years after the expiration of Celgene's original patent—a subset of competitors will be able to enter the market with low volumes of generic Revlimid. There will not be a fully competitive market without limitation until at least January 31, 2026." (**Ex. B**, p. 95).

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[12] (Citing 42 U.S.C. § 1395w-104; 42 C.F.R. § 423.120) ("Medicare Part D rules also forbid individual plans from excluding cancer drugs from their formularies, which limits the negotiating power of individual plans.").

[13] (Citing *Initiative for Medicine, Access, and Knowledge, America's Overspend: How the Pharmaceutical Patent Problem Is Fueling High Drug Prices* (Oct. 2017) (online at www.i-mak.org/wp-content/uploads/2020/10/Excess-Costs-Briefing-Paper-FINAL-2017-10-24-with-cover-rev.compressed.pdf)).

z. Celgene "abus[ed]…[the] government-mandated safety program that limits the distribution of high-risk drugs—to prevent generic manufacturers from purchasing the samples of Revlimid needed to obtain approval of generic versions of the drug." (**Ex. B**, p. 108)

aa. "In 2010, FDA required Celgene to implement a REMS safety program for Celgene's cancer drug Revlimid due to its risk of causing birth defects. When FDA approved Celgene's proposed program, the agency warned Celgene that it is illegal for the company to use its REMS program to 'block or delay approval' of generic versions of the drug. []" (**Ex. B**, p. 124)

bb. "Despite this warning, Celgene used its REMS program—which strictly limits the distribution of Revlimid—to prevent generic manufacturers from purchasing the samples of Revlimid needed to obtain FDA approval of their own generic versions of the drug. An internal Celgene presentation examining whether to implement a REMS program for Revlimid's predecessor drug, Thalomid, stated that one benefit of a REMS program was the 'prevention of generic encroachment.'" (**Ex. B**, p. 124)

cc. "According to FDA, Celgene used its REMS program to prevent or delay 14 generic manufacturers from purchasing sufficient samples of Revlimid to obtain FDA approval. [] When Mylan Pharmaceuticals sought to purchase samples of Revlimid from Celgene in 2013, Celgene cited its REMS program and safety concerns as a reason to delay selling Mylan the samples. []" (**Ex. B**, p. 125; **Ex. C** - FDA Findings)

dd. "Mylan was ultimately forced to sue Celgene for access to the samples. Mylan's economic expert in the case estimated that Celgene's denial of samples had the potential to cost consumers as much as $637 million due to the absence of lower competitive prices for Revlimid.[] The parties settled the case in July 2019, with Celgene paying Mylan $62 million.[]" (**Ex. B**, p. 125-126; **Ex. D** – Mylan Settlement)

ee. "Documents obtained by the Committee show that, internally, Celgene viewed its REMS program as a business strategy for preventing competition. For example, a 2016 presentation identifying corporate goals stated that one way to "shape the operating environment to support [Celgene's] business goals" was to "prevent legislative erosion of [its] REMS program." (**Ex. B**, p. 126).

ff. "In the three years after the 2016 presentation, Celgene—along with the pharmaceutical industry trade association PhRMA—lobbied vigorously against legislative reform that would curb the company's ability to use REMS programs to suppress competition." (**Ex. B**, p. 126)

gg. In the first three quarters of 2021, Celgene spent more than $4.5 million "lobbying against transparency and drug pricing reforms"[14] (**Ex. B**, p. 58)

[14] *See also,* **Ex. J,** *Trump Says 'Massive' Campaign Spending Fuels Rise in Drug Prices* – Identifying Celgene as the third largest donor in 2015-2016.

hh. "According to data provided by Celgene, the cost of its commercial copay program for its cancer drug Revlimid was equivalent to approximately 0.16% of its net U.S. revenue for Revlimid from 2011 to 2018." (**Ex. B**, p. 151; *see also,* **Ex. F – *Congressional Testimony of Defendants' Former and Current CEOs***)

IV. ECONOMIC BACKGROUND

40. For most consumer products, the person responsible for paying for them is also the person selecting them. The pharmaceutical marketplace departs from this norm.

41. Prescription drugs may only be dispensed pursuant to a doctor's prescription, and a licensed pharmacist may dispense only the brand-name drug named in the prescription or its AB-rated, FDA-approved generic equivalent.[15]

42. In most instances, patients and/or their health insurer pay for prescription drugs. Like the pharmacist, their "choice" is limited to the drug named in the prescription or its AB-rated generic equivalent. Therefore, the doctor's prescription defines the relevant product market because it limits the patients' (and pharmacist's) choice to the drug named therein.

43. When there is no generic competition for a brand-name drug, the drug manufacturers can raise drug prices without fear of losing market share. The ability to do this is the result of the brand-name drug company's monopoly power over the market for that drug in both its brand-name and generic form. When an AB-rated generic is available, price is reintroduced to the product selection decision at the pharmacy counter, and the disconnect between choice and payment is lessened, disabling the brand manufacturer from exploiting that disconnect. Generic introduction restores normal competitive pressures.

44. Typically, AB-rated generic versions of brand-name drugs are priced significantly below their brand-name counterparts. When multiple generic manufacturers enter the market,

[15] In many states, pharmacists must substitute an AB-rated generic for a brand-name drug without seeking permission from the prescribing doctor.

prices for generic versions of a brand-name drug predictably decrease, sometimes as much as by 90%, because of price competition among generic manufacturers.[16] The FDA reports that, in 2010, the use of FDA-approved generics saved $158 billion, or $3 billion per week, and that one year after entry, a generic drug takes over 90% of the corresponding brand-name drug's sales at 15% of the price. Generic drug entry, therefore, is a huge threat to the continued profitability of a branded drug.

45. As the price gap between the brand-name drug and its corresponding generic drug widens, the former's sales volume shrinks. Price is the only material difference between a brand-name drug and its AB-rated generic equivalent.

46. For every rung in the prescription drug ladder, except for the brand-name drug manufacturer, there is a financial benefit to choose the generic drug, specifically: (1) pharmacies normally earn a higher markup on generic drugs because of pricing structure and federal reimbursement rules; (2) private health insurers typically offer incentives to pharmacies to fill prescriptions with generics; and (3) to incentivize patients to request generic drugs, health insurers often offer lower co-pays for generic drugs than for brand-name drugs.

47. Generic competition enables purchasers, like Assignors and the Class Members, to purchase a generic version of a brand-name drug at substantially lower prices. However, until generic manufacturers enter the market with an AB-rated generic, unencumbered with volume limitations or other concessions, there will be no generic drug which ***freely*** competes effectively with the brand-name drug, and therefore, the brand-name manufacturer can continue to charge

[16] *See*, *e.g.*, Jon Leibowitz, *"Pay for Delay" Settlements in the Pharmaceutical Industry: How Congress Can Stop Anticompetitive Conduct, Protect Consumers' Wallets, and Help Pay for Health Care Reform* (June 23, 2009), http://www.ftc.gov/sites/default/files/documents/public_statements/pay-delay-settlements-pharmaceutical-industry-how-congress-can-stop-anticompetitive-conduct-protect/090623payfordelayspeech.pdf.

supra-competitive prices without losing sales. Given their acute knowledge of the effects of generic entry into a market, brand-name manufacturers like Celgene have a strong incentive to delay the entry of a generic drug onto the market by engaging in anticompetitive tactics, such as entering into illegal reverse "pay for delay" settlement agreements and filing serial frivolous patent infringement lawsuits.

V. THE REGULATORY BACKGROUND

a. The Hatch-Waxman Act and NDA Approval Process

48. Under the Federal Food, Drug and Cosmetics Act (21 U.S.C. §§ 301-392) ("FDCA"), a manufacturer that creates a new, pioneer drug must obtain the approval of the FDA to sell the new drug by filing a New Drug Application ("NDA"). An NDA must include submission of specific data concerning the safety and efficacy of the drug and identify any patents claiming the drug. 21 U.S.C. § 355(b).

49. When the FDA approves a brand-name manufacturer's NDA, it lists in a publication entitled the "Approved Drug Products with Therapeutic Equivalence Evaluations" (known as the "Orange Book") any patents which, according to the information the brand-name manufacturer supplies to the FDA: (1) claim the approved drug or its approved uses; and (2) for which a "claim of patent infringement could reasonably be asserted if a person is not licensed by the owner engaged in the manufacture, use, or sale of the drug."[17]

50. The FDA *does not* investigate the patents or verify the NDA sponsor's representations for accuracy or trustworthiness prior to listing patents in the Orange Book. It is a purely administrative and clerical act.

51. Once a brand manufacturer lists a patent in the Orange Book, it puts potential generic competitors on notice that the brand manufacturer considers the patent to cover its drug.

[17] 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(g)(7)(A)(iii).

b. The Hatch-Waxman Act and ANDA Approval Process

52. In 1984, Congress amended the FDCA with the enactment of the Hatch-Waxman Act ("Hatch-Waxman").[18] Congress' principal intent was for Hatch-Waxman to simplify and reduce the regulatory hurdles for prospective generic manufacturers, by replacing the lengthy and costly NDA approval process with an expedited ANDA review process.[19] Under Hatch-Waxman, an ANDA applicant may rely on the safety and efficacy findings of the NDA for the referenced brand-name drug if the ANDA demonstrates the proposed generic drug is therapeutically equivalent and "bioequivalent," *i.e.*, it contains the same active ingredient(s), dosage form, route of administration, and strength as the brand-name drug, and is absorbed at the same rate, and to the same extent, as the brand-name drug. For ANDAs that pass this test, the FDA assigns an "AB" rating to the generic drug.

53. Bioequivalence is generally demonstrated via studies in which the proposed generic is compared to the Reference Listed Drug ("RLD," which is, in this instance, the brand-name drug) in either *in vivo* or *in vitro* studies. These studies require the ANDA applicant to have access to sufficient samples of the RLD to conduct the necessary comparisons. Without RLD samples, it is impossible to complete and file an ANDA application.

54. The FDA illuminates the issue:

> To obtain approval for a generic drug, the generic company needs to show, among other things, that its version of the product is bioequivalent to the RLD [i.e., the brand drug, or reference listed drug]. This usually requires the generic company to conduct bioequivalence studies comparing its product to the RLD, and to retain samples of the RLD used in testing after a study is complete. To conduct these kinds of bioequivalence studies, the generic company needs to obtain samples (generally between 1,500 and 5,000 units) of the RLD.[20]

[18] Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) ("Hatch-Waxman").
[19] *Id*.
[20] FDA, *Reference Listed Drug (RLD) Access Inquiries*,

55. Only samples of the RLD approved by the FDA and marketed in the United States may be used for bioequivalence testing purposes. In the ordinary course, a prospective ANDA sponsor obtains samples by buying them, at market price, from a drug wholesaler or distributor. Wholesalers and distributors are large companies that buy drugs from manufacturers for the purpose of re-selling them to pharmacies or other entities. Generic companies are authorized to buy prescription drugs from distributors for bioequivalence testing purposes.

56. However, given the nature of the subject drugs, Celgene's own former senior vice president of global regulatory affairs, drug safety, risk management, and quality assurance Graham Burton testified that Celgene is the only source from which a generic company could obtain Thalomid or Revlimid for purposes of bioequivalence testing.[21]

c. The Hatch-Waxman's Balancing Act

57. As a counterbalance to Hatch-Waxman's simplified ANDA process, Hatch-Waxman also provides brand manufacturers with the ability, merely by filing a patent infringement lawsuit, to easily obtain what is essentially a preliminary injunction, in the form of an automatic stay of up to 30 months of the FDA's ability to approve a generic manufacturer's ANDA.

58. To obtain FDA approval of an ANDA, the generic manufacturer must certify that it will infringe no patent listed in the Orange Book claiming the brand drug, because either:

a. No patent for the brand-name drug has been filed with the FDA (a "Paragraph I Certification");

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https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm (last visited Feb. 26, 2019).

[21] Exhibit to Brief in Opposition to Motion for Summary Judgment at PageID 69-70, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018) ECF No. 285-15 ("MSJ Opp.").

b. The patent for the brand-name drug has expired (a "Paragraph II Certification");

c. The patent for the brand-name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III Certification"); or

d. The patent for the brand-name drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV Certification").[22]

59. When a generic manufacturer files a Paragraph IV Certification, it must notify the brand manufacturer and patent owner. The ANDA filing itself becomes an artificial act of patent infringement, entitling the patent holder to sue for injunctive relief, according to Hatch-Waxman.

60. If the patent holder sues the ANDA filer within 45 days of receiving the Paragraph IV Certification, Hatch-Waxman prevents the FDA from granting final approval to the ANDA until the earlier of (a) 30 months after the lawsuit is commenced, or (b) the court presiding over the patent infringement action rules that the patent is invalid or not infringed by the ANDA.[23] It is almost always the case that the 30 months expire before the court rules, resulting in a 30-month statutory stay.

61. However, during the 30-month stay, the FDA may grant "tentative approval" to an ANDA applicant if the agency determines that the ANDA would qualify for final approval, but for the 30-month stay.

62. Hatch-Waxman grants a 180-day period of market exclusivity to the first Paragraph IV ANDA applicant ("first filer") to file a substantially complete ANDA. During the 180-day exclusivity period (measured from the first commercial marketing of the generic drug or the date of a court decision finding the listed patent invalid, unenforceable, or not infringed),[24] the first

[22] 21 U.S.C. § 355(g)(2)(A)(vii).
[23] 21 U.S.C. § 355(j)(5)(B)(iii).
[24] 21 U.S.C. § 355(j)(5)(B)(iv)); *see also* 21 C.F.R. § 314.107(c)(1)).

ANDA filer enjoys 180 days of freedom from competition from other generic versions of the drug, and during that period can capture almost all of the market for the drug while selling the generic for a higher price than the market will support once additional generics enter the market.

63. The Medicare Prescription Drug Improvement and Modernization Act of 2003 ("MMA") set forth numerous conditions under which a first filer forfeits its 180-day exclusivity, thereby allowing other ANDA filers to enter the market.[25] For example, forfeiture occurs if the first filer fails to obtain tentative approval within 30 months from filing, unless the failure is caused by a change in, or review of, the approval requirements.

64. Under the "Agreement with another applicant" provision, the first filer will forfeit its exclusivity if it "enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the [Paragraph IV certification] . . ."[26]

65. Under the "failure to market" provision, a first filer forfeits its 180-day exclusivity if it fails to market its generic drug by the *later of*:

> (a) *the earlier* of the date that is:
>
> (1) 75 days after receiving final FDA approval; or
>
> (2) 30 months after the date it submitted its ANDA; or
>
> (b) the date that is 75 days after the date as of which, as to each of the patents qualifying the first applicant for exclusivity (i.e., as to each patent for which the first applicant submitted a Paragraph IV Certification), at least one of the following has occurred:
>
> (1) a final decision of invalidity or non-infringement;
>
> (2) a settlement order entering final judgment including a finding the patent is invalid or not infringed; or

[25] Public Law 108-173; 21 U.S.C. A. § 355(j)(5)(D).
[26] 21 U.S.C. § 355(j)(5)(D)(i)(V).

(3) the NDA holder delists the patent from the Orange Book.[27]

66. Branded-manufacturers and first filers can structure an agreement to circumvent the above provisions and keep the 180-day exclusivity in place by, among other things, settling their litigation before a final judgment of invalidity or non-infringement can be entered, or by seeking a consent judgment that does not include a finding that all the patents for which the first filer submitted a Paragraph IV Certification were invalid or not infringed. Consequently, a subsequent ANDA filer can fight this only by obtaining a judgment that all patents for which the first filer filed a Paragraph IV Certification are invalid or not infringed, thereby triggering forfeiture of the first filer's 180-day exclusivity rights.

d. The REMS Programs

67. Since at least the 1960s, the FDA has examined and implemented various methods for managing risks related to pharmaceutical products. Methods have included disclosure and labelling requirements. The Controlled Substance Act of 1970 regulated manufacturers, prescribers, dispensers, and labels and permitted the FDA to require warnings on packages.[28]

68. In the 1990s, the FDA began to work with manufacturers to develop risk management programs for drugs with dangerous side effects. In the 2000s, the FDA established Risk Minimization Action Plans ("RiskMAPs"), in which manufacturers voluntarily instituted risk minimizing plans.

69. In 2007, Congress passed the Food and Drug Administration Amendments Act ("FDAAA"), which codified the Risk Evaluation and Mitigation Strategies ("REMS") to be implemented with respect to certain pharmaceutical products "that have already been approved"

[27] 21 U.S.C. § 355(j)(5)(D)(i)(I).
[28] 21 U.S.C. § 801, *et seq.* (2002).

and directs the Secretary of Health and Human Services ("HHS") to establish an active post-market drug surveillance infrastructure.[29]

70. A REMS can include, *inter alia*, a medication guide, patient package inserts, and/or restrictions on the distribution of the drug.

71. Since their enactment in 2007, REMS have been increasingly common in the FDA approval process; roughly 40% of new drugs have REMS programs.

72. REMS are intended to give the FDA authority to condition drug approval on the implementation of a program designed to address serious risks associated with certain pharmaceutical products. The intention is not to make drugs, or drug samples, less available. In fact, §505-1(f)(8) explicitly prohibits brand manufacturers from using REMS to "block or delay approval of" an ANDA. The FDAAA does not prohibit the sale of REMS-subject drugs to generic manufacturers that will use those drugs in controlled bioequivalence testing, nor does it give an NDA holder the right to interfere with a competitors' ability to purchase necessary drug samples.

e. Brand Manufacturers Have Abused REMS to Block Generic Competition

73. Competition from generics dramatically reduces a brand manufacturer's profits as prices erode and the brand loses market share. Brand manufacturers are therefore highly motivated to delay or block generic entry by extending their monopoly beyond its legal limits. Brand manufacturers have come to do this through, *inter alia*, abusing and "gaming" REMS programs. In 2016, Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research ("CDER") testified that brand companies use REMS programs "as an excuse to not give the drug to the

[29] 21 U.S.C. § 355-1(f)(8).

generics so they can compare it to their drug." This behavior, she noted, causes "barriers and delays in getting generics on the market."[30]

f. State and Federal Governments Recognize the Anticompetitive Harm of REMS Abuse and Targeted REMS Abuse

74. REMS abuse has come under increasing scrutiny as generics' resulting inability to enter the market has caused real and substantial harm to the American public by increasing U.S. healthcare costs by more than $5 billion annually.[31]

75. In June 2016, the Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights, held a hearing on a bill entitled "Creating and Restoring Equal Access to Equivalent Samples Act of 2016" ("CREATES Act"). The bill proposed creating an independent cause of action for refusal to supply samples by a manufacturer of a product subject to REMS under certain circumstances. Senator Patrick Leahy (D-VT) commented:

> The first delay tactic addressed by the CREATES Act involves withholding of drug samples that generic manufacturers need to gain regulatory approval. Federal law requires generic competitors to prove that their low-cost alternative is equally safe and effective as the brand-name drug with which they wish to compete. Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition.[32]

76. Senator Chuck Grassley (R-IA), in that same hearing, echoed Senator Leahy:

> So I was concerned when we heard of other tactics that appeared to frustrate the intent of the Hatch-Waxman Act – a law enacted to

[30] *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. 31 (2016) (testimony of Janet Woodcock, Director, Center for Drug Evaluation & Research).
[31] Association for Accessible Medicines, *Increase Competition & Access – Support CREATES Act*, https://accessiblemeds.org/campaign/increase-competition-and-access-rems (last visited Feb. 26, 2019).
[32] Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Statement of Senator Patrick Leahy (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-leahy-statement-2.

> streamline and expedite the approval process for generic drugs. We heard that certain brand drug companies were misusing their [REMS] to withhold access to drug samples for [BE] testing and generic drug development in violation of FDA regulations and the Hatch-Waxman Act…. These strategies basically amount to brand drug companies using an FDA regulatory process set up as a safety measure, to instead block generic competition.[33]

77. The bill was reintroduced to the Senate on April 27, 2017, and reported to the Senate Judiciary Committee on June 21, 2018. The bill received sweeping support from Republican Senators Ted Cruz and Mike Lee, as well as Democratic Senators Dianne Feinstein and Sheldon Whitehouse. Both liberal and conservative lobby groups support the bill. If enacted, the CREATES Act would save the government as much as $3.8 billion over a ten-year period as it would increase generic drug production and lower government Medicare and Medicaid costs.

78. Some estimates on the cost of REMS abuse are as high as $5.2 billion on the federal government, $5.8 billion on private insurers, and $1.8 billion for ordinary American consumers.[34]

79. Noticeably, the Pharmaceutical Researchers and Manufacturers of America, with Executive Chairman, Robert Hugin (former CEO of Celgene between 2010 and 2017, and thereafter its Executive Chairman), opposed the bill. Reportedly, "drug company executives . . . pour[ed] into Washington on private jets . . . to push for blocking the CREATES Act from the budget agreement."[35]

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[33] Hearing Before the Senate Judiciary Committee Subcommittee on Antitrust, Competition Policy and Consumer Rights on "The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition," Prepared Statement of Senator Chuck Grassley, Chairman (June 21, 2016), https://www.judiciary.senate.gov/download/06-21-16-grassley-statement.

[34] Alex Brill, *Unrealized Savings from the Misuse of REMS and Non-REMS Barriers* (Sept. 2018), https://accessiblemeds.org/sites/default/files/2018-9/REMS_WhitePaper_September2018%5B2%5D.pdf.

[35] David Dayen, *Senate Republicans Kept Provision to Fight High Drug Prices Out of Spending Bill, Democrats Say*, THE INTERCEPT (Feb. 8, 2018), https://theintercept.com/2018/02/08/spending-bill-creates-act-drug-prices/.

80. Similarly, Representative David McKinley of West Virginia introduced the FAST Generics Act bill on April 6, 2017.[36] The bill would require that brand-name manufacturers "not construe or apply any condition or restriction relating to the sale, resale, or distribution of the covered product, including any condition or restriction adopted, imposed, or enforced as an aspect of a [REMS] strategy, in a way that restricts or has the effect of restricting the supply of such covered product to an eligible product developer for development or testing purposes." The bill was referred to the House Subcommittee on Health on April 7, 2017.

81. In an effort to combat rampant REMS abuse and to facilitate access to samples of REMS-subjected drugs, the FDA began issuing "safety determination" letters to brand companies that confirmed that the FDA would not consider providing samples of the RLD for generic bioequivalence testing to be a violation of REMS. In 2014 the FDA stated:

> In the interest of facilitating prospective generic applicants' access to RLD supplies to conduct the testing necessary to support ANDA approval, FDA has, on request, reviewed the [generic's] BE study protocols proposed by prospective ANDA applicants to assess whether they provide safety protections comparable to those in the applicable REMS ETASU. When the Agency has determined that comparable protections existed, FDA has issued letters to the RLD sponsors stating so and indicating that FDA would not consider it to be a violation of the REMS for the RLD sponsor to provide drug product to the prospective ANDA applicant.[37]

[36] Fair Access for Safe and Timely Generics Act of 2017, H.R.2051, 115th Congress (1st Session 2017).

[37] FDA Center for Drug Evaluation and Research, *Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD* (Dec. 2014), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-letter-fda-stating-bioequivalence-study-protocols-contain-safety-protections-comparable* ("2014 Draft Guidance").

82. Despite their efforts to help generic manufacturers by issuing such letters, the FDA continues to reiterate that there is no requirement that a generic company seek or obtain such a letter from the FDA: "Requesting or obtaining such a letter from FDA is not a legal requirement."[38]

83. In 2016, a Senate committee concluded that the FDA has "attempted to stymie [brand manufacturers'] obstruction" by providing letters to generic companies indicating that the agency "see[s] no safety risk," but its "actions have been largely ineffective."[39]

84. In 2017, the FDA committed to responding to generic manufacturers' inquiries seeking help accessing samples within 60 days of receipt to mitigate and shorten the delay brand-manufacturers' scheme imposes.

85. On July 27, 2017, the Federal Trade Commission ("FTC") in a Prepared Statement delivered to the United States House of Representatives Subcommittee on Regulatory Reform, Commercial and Antitrust Law warned that "[d]espite clear guidance from both Congress and the FDA that drug firms should not use REMS programs to block or delay generic or biosimilar competition, complaints about abuse of the regulatory process persist . . . [o]ne study estimates that Americans have lost $5.4 billion in annual savings due to delays in accessing drug samples caused by REMS misuse and other non-FDA mandated restricted distribution programs." In that statement, the FTC explicitly referenced Celgene's actions with respect to Thalomid and Revlimid.

86. On May 17, 2018, the FDA announced that it would begin to regularly publish a list of brand-name drugs that have been the target of complaints that their NDA-holder (or

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[38] FDA Center for Drug Evaluation and Research, *Draft Guidance: How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD* (Dec. 2014), *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-obtain-letter-fda-stating-bioequivalence-study-protocols-contain-safety-protections-comparable*

[39] *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System,* Senate Special Comm. on Aging, 114th Cong. 115 (December 2016), https://www.aging.senate.gov/imo/media/doc/Drug%20Pricing%20Report.pdf.

manufacturer) is denying access to samples of RLDs when generic companies seek to buy them. The initial list confirmed that the FDA sent at least 21 safety determination letters to at least six brand companies, including Celgene. Its larger list documented 57 different drugs with annual combined sales of $13.0 billion, to which sample access had been denied.

87. Celgene is identified on the list in connection with three drugs, as FDA received numerous access inquiries for Celgene's Thalomid, Revlimid, and a third drug not subject to this Amended Complaint, Pomalyst (pomalidomide). The FDA received ten inquiries related to Thalomid, thirteen inquiries related to Revlimid, and eight inquiries related to Pomalyst. The FDA issued at least four safety letters for Revlimid, including on July 21, 2012, May 19, 2014, February 22, 2017, and August 15, 2017. The FDA issued safety letters for Thalomid on December 12, 2007, and January 17, 2008.

88. FDA Commissioner Scott Gottlieb stated:

> Today, we're making public a list of companies that have potentially been blocking access to the samples of their branded products. We hope that this increased transparency will help reduce unnecessary hurdles to generic drug development and approval. We often hear of these tactics when it comes to generic drug developer access to samples when the brand products are subject to limited distribution programs. In some cases, these limitations on distribution may be asserted relating to a Risk Evaluation and Mitigation Strategy ("REMS"), a program that the FDA implements for certain drugs to help ensure that the benefits of these drugs outweigh their risks.[40]

89. Gottlieb, in an earlier speech noting the pervasiveness of REMS abuse commented "My message is this: end the shenanigans." He continued:

> [B]randed companies' use of REMS — which FDA adopts as a way to ensure the safe use of certain drugs — is also sometimes being used as a way to frustrate the ability of generic firms to purchase the

[40] *Statement from FDA Commissioner Scott Gottlieb, M.D., on new agency efforts to shine light on situations where drug makers may be pursuing gaming tactics to delay generic competition*, FDA (May 17, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm.

> doses of branded drug that they need to run their studies. This needs to stop… I consider these tactics unfair and exploitative practices, and they're in direct conflict with our broader public health goals.[41]

90. Then, in a statement given to the HHS in July 2018, the FTC urged action that "carefully considered regulatory and legislative efforts to address REMS abuse." The FTC went on that "[b]y improperly blocking the product developer from obtaining samples, the branded manufacturer can potentially delay or indefinitely block generic or biosimilar competition to its product, thereby reducing the competition that Congress specifically sought to facilitate via the Hatch-Waxman Act . . ."[42]

91. On October 3, 2018, the FTC delivered a prepared statement before the Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights, noting that brands continue to "misuse REMS restrictions to prevent or delay generic firms from obtaining FDA approval for lower cost drugs . . ."[43]

92. On December 20, 2019, Congress enacted material portions of the CREATES Act. It establishes a standalone private right of action for qualifying developers of generic drugs to sue branded drug manufacturers, like Celgene, that refuse "to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms."

93. The passage of the bipartisan bill confirms the anticompetitive harm inflicted by brand manufacturers, like Celgene, that abuse the REMS process to unlawfully monopolize the market for a drug by excluding generic competition beyond the period in scope afforded by a

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[41] Scott Gottlieb, M.D., Commissioner of Food and Drugs, Remarks at the Federal Trade Commission: Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics (Nov. 8, 2017), https://www.fda.gov/NewsEvents/Speeches/ucm584195.htm

[42] *Id.*

[43] *Oversight of the Enforcement of the Antitrust Laws,* Prepared Statement of the Federal Trade Commission before the Subcommittee on Antitrust, Competition Policy and Consumers Rights, Judiciary Committee, U.S. Senate (Oct. 3, 2018).

lawfully obtained patent. CREATES acknowledges the rampant abuse of the REM system by manufacturers like Celgene and seeks to mitigate the harm that such unlawful behavior has and continues to impose on the American market for drugs. As such, CREATES is a confirmation of the central unlawfulness of REMS abuse and an attempt to pragmatically address it.

94. The need to address REMS abuse through CREATES was not a function of any ambiguity in the law, but rather an acknowledgement that a unified chorus of regulatory officials and legislators had failed to deter REMS abuse despite years of denunciations, issuing of nonbinding comments, investigations, and public shaming, which often singled out Celgene's REMS abuse in connection with the subject drugs in this case.

g. The Citizen Petitions

95. Section 505(j) of the FDCA creates a mechanism that allows a person to file a petition with the FDA requesting that the agency take, or refrain from taking, any form of administrative action. This is known as a "citizen petition."

96. A citizen petition allows a citizen to notify the FDA of its genuine concerns about safety, scientific or legal issues regarding a product at any time before or after it enters the market.

97. Pursuant to FDA regulations, the FDA Commissioner must respond to a citizen petition within 180 days of receipt with a grant in whole or in part, or a denial of the petition. The Commissioner can provide a tentative response with an estimate on a time for a full response.

98. Gary Buehler, R.Ph., former Director of the Office of Generic Drugs ("OGD"), at CDER, noted that of 42 citizen petitions raising issues about the approvability of generic products, "very few . . . have presented data or analysis that significantly altered the FDA's policies." Despite this, *it is standard practice for the FDA to withhold ANDA approval until it has completed its research into, and responded to, a citizen petition*.

99. Responding to a citizen petition strains the FDA's limited resources. Regardless of how frivolous a petition may be, the FDA must expend considerable resources researching the petition's scientific, medical, legal, and economic issues, delaying ANDA approval, even if a petition is later found to be baseless.

100. Frivolous petitions sponsored by branded drug manufacturers have become an increasingly common tactic to delay generic competition.

101. In many cases, citizen petitions have been filed relating to ANDAs that have been pending for over a year, long after the brand manufacturer received notice of the ANDA filing. In these cases, the petition delays the ANDA approval while the FDA evaluates the citizen petition. In most cases, there is no reason for the brand manufacturer's delay in filing the citizen petition.

102. The FDA has acknowledged manipulation of the citizen petition review process. Former FDA Chief Counsel Sheldon Bradshaw recognized that during his tenure he had "seen several examples of citizen petitions that appear designed not to raise timely concerns with respect to the legality of scientific soundness of approving a drug application but that to try to delay the approval simply by compelling the agency to take the time to consider arguments raised in the petition whatever their merits and regardless of whether or not the petitioner could have made those very arguments months and months before."[44]

h. Patent Prosecution

103. Filing a patent application is an *ex parte* process for which the law imposes a duty of good faith, candor, and disclosure on the filing party.[45] This duty requires the filer, including

[44] 153 Cong. Rec. 127 (Jan. 4, 2007) (statement of FDA Chief Counsel Sheldon Bradshaw in 2005).
[45] *See* 37 C.F.R. § 1.56; Manual of Patent Examining Procedure § 2000.

his or her agents, attorneys, or anyone else involved in the prosecution, to disclose all material information on the patentability of the claims.

104. An applicant's intentional withholding of information known to be material to patentability with the intent to deceive the USPTO constitutes inequitable conduct and renders a patent unenforceable.

105. The existence of prior art is material to patentability. Prior art means that "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public" or "the claimed invention was described in a patent issued under section 151, or in an application for a patent published or deemed published under section 122(b)."[46]

VI. CELGENE'S ANTICOMPETITIVE CONDUCT

a. Thalomid and Revlimid

106. In the mid-20th Century, thalidomide was marketed as a sleeping pill and anti-morning sickness pill for pregnant women. Devastatingly, when consumed by pregnant women, thalidomide caused life-threatening fetal deformities and birth defects. Adverse effects also included nerve damage.

107. Thalidomide was thereafter banned worldwide, including in the United States. The U.S. ban was in place until July 16, 1998, when the FDA approved Celgene's December 20, 1996, NDA 20-785 for Thalomid, its branded version of thalidomide. The FDA approved Thalomid only as a treatment for ENL, a form of leprosy. But to mitigate fetal exposure to the drug, the FDA conditioned its Thalomid approval on Celgene's use of the System for Thalidomide Education and Prescribing Safety ("S.T.E.P.S.") distribution program, in which patients were required to review

[46] 35 U.S.C. § 102(a)(1)-(2).

educational materials, register with the program, and agree to program restrictions. The FDA noted, in its Thalomid NDA approval, that "[t]hat current restrictions strike a balance between the need to prevent fetal exposure to the drug and the need to make the drug available without extraordinary burdens on patients and prescribers."

108. After the FDA codified its REMS distribution program, the FDA approved Celgene's supplemental application containing a proposed REMS program for Thalomid on August 3, 2010.

109. During that time, Celgene sought and obtained a series of patents which enabled it to create artificial barriers of entry for generic competition by exploiting legal and regulatory loopholes, as further discussed below.

110. Below is a chart representing Celgene's patent protection web:

Patent	Patent Number	Date Filed	Date Issued	Expiration Date	Description	Drugs
Composition of Matter						
'517 Patent	5,635,517	7/24/1996	6/3/1997	10/7/2019	Method of reducing TNF.alpha. Levels with amino substituted 2-(2,6-dioxopiperidin-3-yl)-1-oxo-and 1,3-dioxoisoindolines	Revlimid
'012 Patent	7,230,012	6/30/2003	6/12/2007	12/9/2023	Pharmaceutical compositions and dosage forms of thalidomide	Thalomid
Polymorph						
'800 Patent	7,465,800	9/3/2004	12/16/2008	4/27/2027	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid

’217 Patent	7,855,217	12/15/2008	12/21/2010	11/24/2024	Polymorphic forms of 3-(4-amino-1-oxo-1,3 dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
REMS						
’501 Patent	6,045,501	8/28/1998	4/4/2000	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid, Revlimid, Pomalyst
’976 Patent	6,561,976	9/26/2001	5/13/2003	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid, Revlimid, Pomalyst
’432 Patent	6,908,432	1/22/2004	6/21/2005	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid, Revlimid, Pomalyst
’984 Patent	7,874,984	4/12/2005	1/25/2011	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid
’763 Patent	8,204,763	12/13/2010	6/19/2012	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid, Revlimid, Pomalyst

'188 Patent	8,589,188	5/17/2012	11/19/2013	8/28/2018	Methods for delivering a drug to a patient while preventing the exposure of a fetus or other contraindicated individual to the drug	Thalomid, Revlimid, Pomalyst
'720 Patent	6,315,720	10/23/2000	11/13/2001	10/23/2020	Methods for delivering a drug to a patient while avoiding the occurrence of an adverse side effect known or suspected of being caused by the drug	Thalomid, Revlimid, Pomalyst
'977 Patent	6,561,977	9/27/2001	5/13/2003	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid, Revlimid, Pomalyst
'784 Patent	6,755,784	3/7/2003	6/29/2004	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid, Revlimid, Pomalyst
'399 Patent	6,869,399	1/22/2004	3/22/2005	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid

’018 Patent	7,141,018	1/3/2005	11/28/2006	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’566 Patent	7,959,566	5/19/2006	6/14/2011	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid
’886 Patent	8,315,886	12/13/2010	11/20/2012	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid, Revlimid, Pomalyst
’531 Patent	8,626,531	8/22/2012	1/7/2014	10/23/2020	Methods for delivering a drug to a patient while restricting access to the drug by patients for whom the drug may be contraindicated	Thalomid, Revlimid, Pomalyst
Dosing						
’740 Patent	7,189,740	4/11/2003	3/13/2007	4/11/2023	Methods of using 3-(4-amino-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for the treatment and management of myelodysplastic syndromes	Revlimid

’569 Patent	7,968,569	5/15/2003	6/28/2011	10/7/2023	Methods for treatment of multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’363 Patent	7,468,363	4/8/2005	12/23/2008	10/7/2023	Methods for treatment of cancers using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione	Revlimid
’929 Patent	8,741,929	11/19/2009	6/3/2014	3/8/2028	Methods using 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione for treatment of mantle cell lymphomas	Revlimid
’717 Patent	8,404,717	3/24/2011	3/26/2013	4/11/2023	Methods of treating myelodysplastic syndromes using Lenalidomide	Revlimid
’095 Patent	8,648,095	6/5/2012	2/11/2014	5/15/2023	Methods for treating multiple myeloma using 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl)-piperidine-2,6-dione in combination with proteasome inhibitor	Revlimid
’120 Patent	9,056,120	3/13/2013	6/16/2015	4/11/2023	Methods of treating myelodysplastic syndromes with a combination therapy using lenalidomide and azacitidine	Revlimid
’498 Patent	8,530,498	4/8/2013	10/10/2013	5/15/2023	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydroisoindol-2-yl) piperidine-2,6-dione	Revlimid

'621 Patent	9,101,621	4/17/2014	8/11/2015	5/15/2023	Methods for treating multiple myeloma with 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione after stem cell transplantation	Revlimid
'622 Patent	9,101,622	10/10/2014	8/11/2015	5/15/2023	Methods for treating newly diagnosed multiple myeloma 3-(4-amino-1-oxo-1,3-dihydro-isoindol-2-yl)-piperidine-2,6-dione in combination with dexamethasone	Revlimid
'745 Patent	7,435,745	4/26/2006	10/14/2008	7/31/2019 (est.)	Methods and compositions for inhibition of angiogenesis	Thalomid (not listed in Orange Book)

111. As seen above, Celgene filed, prosecuted, and listed in the Orange Book one patent for the Composition of Matter for Thalomid: the '012 Patent, which was first filed with the USPTO in June 2003. Celgene filed, prosecuted and listed a total of 14 patents in relation to the S.T.E.P.S. and/or REMS programs for controlling Thalomid, and later Revlimid, distribution: the '501 Patent, the '976 Patent, the '432 Patent, the '984 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '399 Patent, the '018 Patent, the '566 Patent, the '886 Patent, and the '531 Patent, all of which were filed with the USPTO between August 1998 and August 2012.

112. Revlimid is an immunomodulatory drug that works against cancer cells by affecting the immune system. It is a thalidomide analogue manufactured and marketed by Celgene. Celgene submitted NDA 21-880 to the FDA on April 7, 2005, which provides for the use of Revlimid to treat patients with transfusion dependent anemia due to low or intermediate-1 risk myelodysplastic syndromes associated with a deletion 5 q cytogenetic abnormality with or without additional

cytogenetic abnormalities. The FDA approved Revlimid on December 27, 2005. Celgene was granted exclusivity for Revlimid as it was a new chemical entity ("NCE"); exclusivity expired on December 27, 2010. Competition, absent anticompetitive misconduct, would normally begin immediately after Celgene's exclusivity expired.

113. Revlimid is subject to a REMS distribution program, RevAssist. The primary goal of the RevAssist program, approved by the FDA, is to prevent fetal exposure to Revlimid. The FDA noted in its December 27, 2005, letter to Celgene that RevAssist is "an important part of the post-marketing risk management for Revlimid."

114. In addition to the patents listed in the Orange Book, Celgene was issued numerous additional patents related to thalidomide and its analogs. According to 21 U.S.C. § 355(b)(1), NDA applicants shall file with the application the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug. Despite not listing these patents, thereby admitting that an infringement claim could not reasonably be asserted, Celgene still made frivolous infringement claims for these patents in response to ANDAs for lenalidomide, as discussed below.[47]

115. As seen in the chart above, Celgene also filed, prosecuted, and listed in the FDA Orange Book three patents for the Composition of Matter for Revlimid; the '517 Patent, which was first filed with the USPTO in July 1996, and the two polymorph patents, the '800 Patent and the '217 Patent, first filed with the USPTO in September 2004 and December 2008, respectively

[47] Celgene also filed and prosecuted several additional patents that it did not list in the Orange Book. They are Patent Nos. 6555554 (the "'554 Patent"), 7119106 (the "'106 Patent"), 6281230 (the "'230 Patent"), 6767326 (the "'326 Patent"), 7977357 (the "'357 Patent"), 8193219 (the "'219 Patent") and 8431598 (the "'598 Patent").

(the "Polymorph patents"). Celgene filed, prosecuted, and listed several patents in relation to the RevAssist program for controlling Revlimid distribution; the '501 Patent, the '976 Patent, the '432 Patent, the '763 Patent, the '188 Patent, the '720 Patent, the '977 Patent, the '784 Patent, the '886 Patent, and the '531 Patent, which were filed with the USPTO between August 1998 and August 2012. Celgene filed, prosecuted, and listed a total of ten patents related to the dosage and methods of treatment for Revlimid; the '740 Patent, the '569 Patent, the '363 Patent, the '929 Patent, the '717 Patent, the '095 Patent, the '120 Patent, the '498 Patent, the '621 Patent, and the '622 Patent, filed with the USPTO between April 2003 and September 2014. Another patent, the '745 Patent, was filed in 2006, and was part of a pattern by Celgene of prosecuting invalid and unenforceable patents to erect an impenetrable "patent fortress" around its Thalomid and Revlimid monopolies.

b. Celgene Abused Its REMS Program as a Pretextual Justification for Refusing to Sell Samples and Illegally Monopolized the Market

116. Both Thalomid and Revlimid are subject to REMS distribution programs that require healthcare providers and pharmacies to be certified in the S.T.E.P.S. or RevAssist programs, respectively, and patients must be enrolled in S.T.E.P.S. or RevAssist. Prescribers and pharmacists must complete registration forms. Females of childbearing potential are required to take a pregnancy test 24 hours prior to starting a course of Thalomid or Revlimid and at least every four weeks during treatment. All prescribers are required to provide contraception and emergency contraception counseling with each new prescription. For every new patient, prescribers must submit to Celgene a signed Patient-Physician Agreement Form that identifies the patient's risk category. The prescriber then receives a letter confirming the patients' enrollment and the patient and prescriber receive an authorization number which is to be written on the prescription. The pharmacy must verify that each prescription has an authorization number that is valid for seven days. The pharmacy must then call Celgene, obtain a confirmation number, and write this number

on the prescription. The prescription is then filled within 24 hours. No more than a 28-day supply may be dispensed at one time.

c. Celgene Maintained Monopoly Power Through the Use of Exclusionary Conduct.

117. RevAssist operates through specialty pharmacies. The S.T.E.P.S. program initially operated in all pharmacies. Only in 2006 did S.T.E.P.S. come to exclusively operate through specialty pharmacies. In internal company emails, Alexis Tosti, Celgene's Market Research Analyst, noted that moving to a specialty pharmacy would "be a hurdle for generic companies," and that "[r]estricted distribution is more likely to keep thalidomide out of the hands of generic companies who need product to test against the generic being developed…"[48]

118. A central part of Celgene's monopolistic anticompetitive scheme to unlawfully monopolize the markets for the subject drugs was to abuse REMS and prevent generic manufacturers from obtaining the necessary samples of Thalomid and Revlimid to perform the bioequivalency testing needed to file an ANDA.

119. Celgene abused its REMS program as a pretextual justification for withholding Thalomid and Revlimid samples from generic competitors. Among the manufacturers that Celgene refused to supply are Mylan Pharmaceuticals Inc. ("Mylan") between 2004 and the present, Lannett Company ("Lannett") in 2006, Exela Pharmsci, Inc. ("Exela") in 2006, Dr. Reddy's Laboratories ("Dr. Reddy's") in 2008 and 2009, Watson Laboratories, Inc ("Watson") in 2009, Teva Pharmaceuticals USA ("Teva") in 2009, and Sandoz Inc. ("Sandoz") in 2012. Celgene also entered into an exclusive supply agreement with a French thalidomide supplier to prevent Barr Laboratories ("Barr") from obtaining that company's thalidomide active pharmaceutical ingredient ("API").

[48] Exhibit to MSJ Opp. at PageID 17672, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 285-20.

120. Celgene's improper use of the REMS program as a shield to refuse to provide samples is contrary to the FDAAA. FDAAA subsection f(8) states that "no holder of [a REMS-covered drug] shall use any element to assure safe use…to block or delay approval of…an [ANDA application]."[49]

d. Celgene's REMS Program is a Post-Marketing Distribution System with No Legal or Practical Relation to the Sales of Samples to Competitors.

121. Celgene's REMS distribution programs are post-marketing, commercial distribution programs. Celgene's REMS protocols do not discuss drug manufacturers conducting business with one another in the pre-marketing, drug development phase. Nor do Celgene's REMS protocols discuss or prevent distribution of samples to drug manufacturers.

122. Generic manufacturers' safety protocols are not required to be FDA-approved for that manufacturer to purchase samples of a REMS-subject drug. Robert West, former Deputy Director of OGD, commented that "a generic manufacturer is not required to submit its protocols to the FDA before commencing bioequivalence studies."[50]

123. Clinical and pre-approval studies are not governed by REMS. In an August 2012 meeting with Celgene, the FDA stated, "Celgene's REMS relates to a marketed situation and not a clinical trial where there is more control regarding administration of the product and the amount given is monitored and very limited."

124. A sample supply of a brand-name drug, including the API, is required to manufacture a generic equivalent. The API is used to conduct the required biostudies and validation testing before the generic manufacturer submits its ANDA.

125. Due to Celgene's REMS program, generic manufacturers are unable to purchase Thalomid and Revlimid samples in the United States through normal wholesale distribution

[49] 21 U.S.C. § 355-1(f)(8).
[50] Exhibit to MSJ Opp. at PageID 17061, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 285-21.

channels. They are therefore forced to seek to purchase the drugs directly from Celgene, with the FDA's endorsement.

i. Celgene Refused to Sell Samples in Order to Block Competition

1. Celgene Refused to Sell Samples to Mylan

126. Celgene refused to sell Thalomid and Revlimid samples to Mylan, the second largest generic pharmaceutical manufacturer in the world.

127. Mylan began developing a generic thalidomide product on September 26, 2003. On October 27, 2003, Mylan requested OGD provide guidance on prospective bioequivalency studies. OGD provided the requested guidance within the following year.

128. On December 22, 2003, Mylan requested thalidomide API from API suppliers GYMA Laboratories of America, Inc. ("GYMA") and Antibioticos to manufacture its formulation of thalidomide. By March 11, 2004, Mylan received thalidomide API from Antibioticos.

129. In September of 2004, after Mylan was unable to gain access to Thalomid samples, the FDA suggested Mylan contact Celgene to request samples. On October 5, 2004, Mylan wrote Celgene a letter through its attorneys requesting to purchase 2,500 Thalomid capsules to conduct bioequivalency studies. Celgene failed to respond. Mylan repeated its request on May 3, 2005. At the time, Mylan had already completed safety training sessions for the handling and testing of thalidomide.

130. In a letter dated June 21, 2005, Celgene explained that pursuant to its S.T.E.P.S. program, Thalomid was not available through normal wholesale channels, and that it was against Celgene's policy to deal with third parties in the sale of Thalomid. Notwithstanding the above, Celgene did not have a single internal discussion finding it would be a violation of S.T.E.P.S. to provide Mylan with Thalomid without FDA approval.

131. In unsealed internal emails from July 6, 2005, Celgene noted that "Mylan has had

difficulty obtaining enough of Celgene's reference product to perform the bioequivalency studies, so its ANDA submission is expected to be delayed until late in the third quarter of 2005."[51]

132. On September 2, 2005, Mylan directly contacted Celgene and requested to purchase 3,360 Thalomid capsules to conduct bioequivalency testing.[52] Mylan explained that the "FDA recommended that we contact you directly to request a sample" of Thalomid for bioequivalency testing, and that "obtaining samples through other traditional channels is nearly impossible."[53]

133. On October 20, 2005, Celgene replied, claiming that it needed additional time to consider the request and "to avoid fetal exposure."[54]

134. On November 15, 2005, Mylan used an intermediary to again request that Celgene sell it Thalomid samples for bioequivalency testing.

135. By December 2005, Mylan completed its scale-up of its experimental thalidomide batch. Mylan had, by that time, captured two-years' worth of stability data. The only remaining step to submitting its ANDA was to conduct bioequivalency studies against the RLD.

136. On December 19, 2005, Celgene stated that it would need the FDA's approval to allow Mylan to purchase samples outside of the S.T.E.P.S. program: "[W]e recommend that you contact the FDA's [Division of Special Pathogen and Transplant Products] to discuss the importance of the S.T.E.P.S. program to them."[55] Celgene claimed that if the FDA then "contacts us in writing and recommends that we violate our S.T.E.P.S. program by providing you with the quantity of THALOMID you request, we will further evaluate your request at that time."[56]

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[51] Exhibit to MSJ Opp. at PageID 18485, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-2.
[52] Exhibit to Brief in Support of Motion for Summary Judgment at PageID 15196, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018), ECF No. 283-4 ("MSJ Moving Papers").
[53] *Id*.
[54] Exhibit to MSJ Opp. at PageID 18488, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-2.
[55] Exhibit to MSJ Moving Papers at PgID 15205, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 283-5.
[56] *Id*.

137. This is contradicted by an internal report created in 2003 at Celgene's request, where Celgene admitted Mylan's patient monitoring system—already in place for another drug it was studying—was robust, comprehensive, and equivalent to the S.T.E.P.S. program.

138. Detailing the manufacturer's procedures, Celgene's report stated that Mylan's safety protocols "currently have very sophisticated patient monitoring systems for their respective clozapine products."[57]

139. Furthermore, the report stated "it can be observed that the clozapine requirements are as comprehensive as the S.T.E.P.S. program. Thus, Ivax and Mylan already have experienced [sic] with sophisticated monitoring systems."[58]

140. Next, on January 11, 2006, Mylan requested FDA assistance to obtain the necessary Thalomid samples required for bioequivalence testing. In its letter, Mylan proposed protocols to ensure avoidance of fetal exposure.

141. In emails dated March 3, 2006, Mylan estimated a Thalidomide launch for May 2010.

142. On February 12, 2007, the FDA replied, requesting an investigational new drug application ("IND") or study protocol so that it could "ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place," as a substitute for the S.T.E.P.S. program.[59]

143. The FDA's response continued:

> It is the FDA's view that certain restrictions are needed to ensure safe use of the drug; however, it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product. The agency believes that such bioequivalence studies

[57] Exhibit to MSJ Opp. at PageID 18304, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-1.
[58] *Id*.
[59] Exhibit to MSJ Moving Papers at PageID 15255, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 283-6.

> can be conducted safely under either an IND or in circumstances that provide alternative assurance of patient safety. To ensure that the intention of Congress in enacting the generic drug approval provisions in section 505(j) is not frustrated by the terms of the S.T.E.P.S. program, FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid (including 200 units for the purpose of conducting bioequivalence (including dissolution) testing and 300 units for a limited number of retained samples) when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects.[60]

144. On May 1, 2007, Mylan produced to the FDA its proposed thalidomide safety protocols, which the FDA reviewed, found "acceptable," and so notified Mylan on September 11, 2007.

145. On November 16, 2007, Mylan notified Celgene of the FDA's approval, which directly addressed Celgene's pretextual justification for not providing samples. Celgene's senior executives and officers all admit that the FDA is the ultimate authority on setting safety standards. Yet, Celgene continued to deny Mylan's and others requests for drug samples for bioequivalency testing, using pretextual and obviously flawed safety concerns as its chief justification.[61]

146. Undeterred, Mylan continued to make requests over the next three years, including on December 4, 2007. Celgene continued to refuse to produce Thalomid samples, using delay tactics including requiring Mylan to produce burdensome, irrelevant, and duplicative information. Meanwhile, Celgene internally admitted that another prospective ANDA filer's request was "deficient in a way that the Mylan request is not."

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[60] *Id*.

[61] On April 21, 2000, the FDA sent Celgene a "Warning Letter" stating that "Celgene ha[d] engaged in promotional activities that state or suggest that Thalomid is safe and effective for use in treating multiple myeloma." With no generics on the horizon, Celgene was willing to play fast and loose with the safe distribution of Thalomid so long as it ensured increased utilization and increased profits.

147. On January 8, 2008, Celgene wrote Mylan requesting more information. Mylan responded on February 25, 2008, writing that it was prepared to provide all requested information and enclosed a confidentiality agreement. Celgene and Mylan negotiated the confidentiality agreement until June 24, 2008, when Celgene sent Mylan the executed agreement. Mylan sent Celgene another letter providing even more information and provided Celgene with proof of liability insurance covering any instances of injury relating to drug's misuse, and further provided an indemnity contract.

148. This contract, which was extensively negotiated, agreed to hold Celgene harmless in the event of any injury or misuse.

149. Celgene wrote Mylan on August 1, 2008, that it was reviewing Mylan's documentation. Celgene's then-Regulatory Counsel testified that as of March 4, 2011, no "businesspeople" at Celgene reviewed any of Mylan's documentation. Confoundingly, Celgene served an interrogatory response in an FTC investigation stating that two former CEOs, Sol Barer and Robert Hugin, "made the decisions on behalf of Celgene regarding Celgene's responses to pharmaceutical companies requesting to purchase Thalomid and Revlimid with legal advice from Celgene's Deputy General Counsel and then-Regulatory and Compliance Counsel." The referenced in-house counsel later testified in a separate litigation that they did not have any input into the requests, could not recall reviewing a single response to one of the information requests submitted to Celgene, or sitting in a meeting in which a response to a prospective ANDA filer's request was discussed. In other words, based on testimony provided by Celgene's own in-house counsel, Celgene lied to the FTC in its interrogatory response.

150. In a June 24, 2009 letter, Celgene wrote Mylan alleging there were "outstanding issues" with the information Mylan provided and requested nine additional categories of information. An internal Celgene email dated May 22, 2009, contained a project titled

"Thalidomide Multiple Myeloma." The summary of the project stated "A generic thalidomide application was successfully delayed until at least June '09 in the USA. Celgene may further extend its exclusivity in the USA by using bioequivalence as a generic defense strategy . . ." Celgene's own emails show that it was never truly concerned with the safe distribution of its drugs, but rather used safety as a pretextual justification to prevent generic competition.

151. Celgene's refusal to sell Mylan samples, despite the existence of liability insurance and an indemnity contract, is further evidence Celgene was unwilling to negotiate in good faith with generic manufacturers to provide the requested drugs. This Court previously found, based on these facts, that one could reasonably infer "that Celgene had no objectively legitimate business justification for not selling Mylan samples of Thalomid or Revlimid samples after FDA approval of Mylan's study protocols."[62]

152. Mylan estimates that had Celgene provided it with Thalomid samples in 2006, it would have filed a Paragraph IV Certification, Celgene would have initiated a patent infringement litigation and Mylan could have ultimately entered the thalidomide market in the third quarter of 2010.

153. By June 2007 Mylan began to develop its generic Revlimid. In internal emails from September 2007, Mylan planned to file its ANDA on December 27, 2009, was actively sourcing raw materials, had opinions on the blocking compound patents and planned to design around the formulation patent.

154. In early 2009, Mylan endeavored to purchase lenalidomide supplies to manufacture a generic version of Revlimid. Celgene engaged in more delay tactics, causing Mylan to cease development efforts at various points while it attempted to procure Revlimid samples. Mylan manufactured its final lenalidomide formulation in June 2015.

[62] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094, ECF No. 287, 35 (D.N.J. Oct. 3, 2018).

155. In June 2010, in response to FTC interrogatories, Celgene explained to the FTC that "Celgene has decided not to sell REVLIMID at the present time to manufacturers."[63]

156. Over two years later, through its counsel, Celgene wrote to the FTC that it was willing to "continue selling Thalomid and begin to sell Revlimid to drug companies, branded or generic, in quantities authorized by the FDA sufficient to conduct bio equivalence studies for the purpose of preparing an Abbreviated New Drug Application [ANDA] with the FDA." Celgene, at no point prior to this email, ever sold Thalomid to generic drug companies to support bioequivalency studies for the purpose of preparing ANDAs. Celgene's letter continued: "[Celgene would] seek to set appropriate conditions with the FDA for the sale of Revlimid similar to those it has set for the sale of Thalomid . . . ."

157. On August 14, 2012, Celgene wrote to the FDA claiming that the FDCA does not require an RLD sponsor to provide drug product to a proposed ANDA filer, and that FDA does not have authority to mandate any such requirement. Celgene even threatened that "any sale of Revlimid to a generic manufacturer will not be effectuated unless and until the FTC and the State of Connecticut Attorney General agree to close their investigation."[64]

158. On May 1, 2013, Mylan requested to purchase Revlimid samples from Celgene at market value. On May 14, 2013, Celgene wrote to Mylan that it would sell Revlimid to Mylan upon Celgene's review of Mylan's request and supporting documentation.

159. While not required to do so, Mylan sought FDA approval of its proposed safety protocols to avail itself of any assistance the FDA might be able to offer in procuring Revlimid samples. The FDA approved Mylan's protocols on July 29, 2013.

[63] Exhibit to MSJ Opp. at PageID 18669, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-4.
[64] Exhibit to MSJ Opp. at PageID 17053, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 285-15.

160. On March 11, 2014, Mylan wrote to Celgene explaining that it received all necessary approvals from the FDA. Celgene continued to refuse to provide samples, even, once again, after being informed of FDA approval for the proposed BE testing and safety protocols.

161. On March 20, 2014, Celgene again wrote to Mylan refusing to sell Mylan Revlimid samples. Exasperated with Celgene's tactics, Mylan brought a suit on April 3, 2014 against Celgene under federal and state antitrust laws for its anticompetitive tactics to maintain monopoly power in the market for Thalomid and Revlimid.

162. Mylan alleged that Celgene cited safety concerns as a pretext for its continued refusal to provide samples of Thalomid and Revlimid, and that Celgene used a "playbook of obstruct[ion]" and "gam[ed] the regulatory system."[65]

163. On May 19, 2014, the FDA notified Celgene that it accepted Mylan's submitted lenalidomide safety protocols and reiterated the FDCA's prohibition of using REMS to prevent ANDA filers from accessing drug samples.

164. The FTC filed an amicus brief in support of Mylan's suit against Celgene. The FTC noted that the FDAAA was intended to prevent brand-name manufacturers from using REMS programs to impede generic competition, as Celgene was doing with Thalomid and Revlimid.

165. Further, in August 2012, the FTC sent counsel for Celgene an email detailing "a number of questions" raised by "the Bureau of Competition and the staff of the Connecticut Attorney's General office."[66]

166. These concerns included questions surrounding why Celgene had yet to provide samples of Thalomid to those requesting it, despite receiving explicit authorization from the FDA to do so.

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[65] *Mylan Pharma Inc. v. Celgene Corp*. at ¶ 8, No. 14-cv-2094 (D.N.J. Apr. 3, 2014) ECF No. 1.
[66] Exhibit to MSJ Opp. at PageID 17354-55, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 285-16.

167. The letter also questioned what else Celgene would need to receive in order to authorize the sale of Revlimid to generic manufacturers: "in the interest of advancing our discussions and trying to reach a prompt resolution with you, we propose the FTC and Celgene meet together with the FDA . . . to discuss what Celgene thinks it needs from the FDA in order to be able to make prompt sales to generic firms."[67]

168. The FTC's Bureau of Competition ("BOC") followed up on this letter with another round of correspondence in February 2013.

169. In an e-mail to Celgene's counsel, Richard A. Feinstein, the director of the BOC stated "there is a lot of concern here-at both the Bureau and Commission levels- about the time it has taken for your client to [redacted] of Revlimid capsules for bio-equivalence testing…the Commission's patience is wearing thin. We have reached a point where the staff may be instructed in the very near future to commence litigation."

170. Counsel for Celgene quickly forwarded this email to Celgene executives.

171. Most of Mylan's claims survived Celgene's motion to dismiss. Celgene subsequently filed its motion for summary judgment. On October 3, 2018, Celgene's motion was granted in part and denied in part.[68]

172. One of Mylan's expert witnesses in that litigation, Paul J. Jarosz, Ph.D., stated that Mylan's development process was typical for the pharmaceutical industry and that "[h]ad Mylan been able to purchase Thalomid so that it could dose its bioequivalence studies and receive an approval for its generic drug application, Celgene's '012 Patent and claim 2 of its '327 Patent

[67] *Id*.
[68] *Mylan Pharma Inc. v. Celgene Corp.*, No. 14-cv-2094-ES-MAH (D.N.J Oct. 3, 2018) ECF No. 287.

would have not have prevented Mylan from launching its generic thalidomide product as the claims are invalid due to prior art and/or Mylan's formulation does not infringe them."[69]

173. Regarding generic Revlimid, Dr. Jarosz stated that "based on the simple nature of Revlimid and Mylan's previous experience developing thalidomide, it appears that Mylan could have developed and filed an application for generic lenalidomide product by December 27, 2009."[70]

174. Dr. Jarosz's report confirms that the inability of generic drug manufacturers to bring versions of Thalomid and Revlimid to market were not due to internal issues or manufacturing defects. Instead, his report reinforces the fact that the only barrier to entry in the market was Celgene's anticompetitive conduct.

175. Mylan never received Revlimid samples. Celgene's continued refusal to provide samples of Thalomid and/or Revlimid only further elucidates that Celgene's refusal based on safety concerns was and continues to be a conveniently fabricated excuse to create artificial barriers of entry and frustrate competition.

176. On August 1, 2019, Celgene announced that it reached a settlement with Mylan. On August 8, 2019, the District Court entered a consent judgment dismissing all claims with prejudice. Celgene disclosed that it agreed to pay $62 million to Mylan to resolve all claims. (**Ex. D**–Mylan Settlement.

2. Mylan's Strong Safety Protocols Confirm and Illustrate The Pretextual And Unlawful Nature Of Celgene's Refusal To Sell Samples To Would Be Competitors

177. In September 2011, Sofgen Pharmaceuticals ("Sofgen") contacted Mylan regarding the potential purchase of Amnesteem for bioequivalency testing.

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[69] Exhibit to MSJ Opp. at PageID 17757, *Mylan*, No. 14-cv-2094 (D.N.J) ECF. No. 285-21.
[70] *Id.*

178. Like lenalidomide and thalidomide, Amnesteem is a known human teratogen, and was under FDA restriction for sale and delivery.

179. Sofgen knew of these restrictions and reached out to the FDA prior to contacting Mylan to receive an assurance its iPLEDGE safety restrictions were acceptable and allowed it to receive a drug known to be a human teratogen.

180. The FDA sent Sofgen a letter in response, confirming Sofgen's iPLEDGE procedures were adequate under current FDA guidelines.

181. Mylan and Sofgen entered into successful negotiations surrounding Sofgen's purchase of Amnesteem samples from Mylan. This included the drafting of an indemnity agreement, discussions on the purchase price, and the method for payment and delivery. The sale was completed, and samples were delivered to Sofgen in Spring 2011.

182. Unlike Celgene, Sofgen and Mylan's discussions surrounding the purchase of Amnesteem show that receiving an approval letter from the FDA removes any perceived roadblocks to sharing a drug sample for bioequivalency testing.

183. Mylan's contract with Sofgen shows the process for obtaining generic drug samples can be completed in a short timeframe, and without the unnecessary and burdensome documentation Celgene requested from numerous generic manufacturers.

184. Further, another expert hired by Mylan in its lawsuit against Celgene, Jeff Fetterman, opined that Mylan's experience with the REMS process was robust and extensive, and it would have no issues implementing one for generic thalidomide and lenalidomide.[71]

[71] Exhibit to MSJ Opp. at PageID 18325-70, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-2.

185. As Mr. Fetterman stated in his report, "Mylan has extensive experience developing, implementing, and managing risk management programs, including several REMS programs with the same or similar restrictions and requirements as the S.T.E.P.S. and RevAssist programs."[72]

186. Mr. Fetterman continued and stated "[i]f Celgene had provided brand samples to Mylan and cooperated in developing a shared REMS program for thalidomide, the SS REMS development and FDA approval likely would have taken 18 to 24 months. Furthermore, this estimate may be conservative, as an alternative parallel agreement to sign onto the S.T.E.P.S. program would have taken even less time, possible in as few as 12 months. All of this work could have begun in advance of Mylan's ANDA approval . . . ."[73]

187. Mr. Fetterman's report details further how Celgene's refusal to provide drug samples on the basis of noncompliance with REMS procedures was a misdirection and stall tactic not based in truth or fact.

3. Celgene Refused to Sell Samples to Exela.

188. On May 31, 2006, Exela contacted Celgene and informed it of Exela's intention to file an ANDA for Thalomid. Exela stated it was having difficulty obtaining samples of this drug from other channels, much like the other generic manufacturers who had contacted Celgene. Exela requested a proposal for purchase within 10 days.

189. On June 27, 2006, Exela sent a follow up letter to Celgene again requesting to purchase Thalomid samples. In its letter, Exela noted the 10-day window for a purchase proposal had lapsed despite being received the day after it was sent.

190. On September 11, 2007, OGD wrote to Exela that its "proposed bioequivalence study protocol comparing Thalidomide Capsules, 200 mg to [Thalomid] is acceptable…."

[72] *Id.* at PageID 18327.
[73] *Id.* at PageIDs 18355-56.

191. On December 11, 2007, OGD Director Gary J. Buehler sent a letter to Celgene's internal regulatory counsel, Kerry Rothschild stating that "FDA has reviewed the bioequivalence protocol submitted . . . on behalf of Exela and has received sufficient assurance that the bioequivalence study will be conducted in such a manner as to ensure the safety of the subjects and has determined that Celgene may provide Exela with 500 units of Thalomid as indicated in FDA's letter to you dated February 8, 2007 for the purposes of conducting an in vivo bioequivalence study and in vitro dissolution testing."

192. Over a year later, on January 8, 2008, counsel for Celgene contacted counsel for Exela regarding the Thalomid purchase request.

193. In a response almost identical to ones given to other generic manufacturers, Celgene stated it did not believe it was obligated to turn over any samples. However, it continued that if Exela were to comply with a list of 10 demands for information, including, for example, proof of liability insurance and a history of product loss due to improper handling or tracking, Celgene would then "reconsider" its denial.

194. Upon information and belief, despite compliance, Celgene never provided Exela with the requested samples of Thalomid.

4. Celgene Refused to Sell Samples to Lannett.

195. On September 6, 2006, Lannett wrote a letter to the FDA requesting bioequivalency recommendations regarding thalidomide capsules.

196. The FDA's OGD responded to Lannett's letter on February 12, 2007. The OGD stated that "it is not the agency's intention to permit the restrictions of the S.T.E.P.S. program to prevent manufacturers of generic drugs from obtaining Thalomid for use in the bioequivalence testing necessary to obtain approval of an abbreviated new drug application for a thalidomide product."

197. The OGD commented that, to ensure Congress' intentions in enacting the Generic Drug Approval Provisions in Section 505(i) are carried out, the "FDA has notified Celgene that the agency intends to exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid . . . for the purpose of conducting bioequivalence testing."

198. The FDA did so notify Celgene, on February 8, 2007, that "a study protocol would be reviewed by the FDA to ensure that all appropriate safeguards for a clinical investigation with thalidomide are in place" if a proposed generic manufacturer wished to conduct bioequivalency studies. The FDA explained that it would "exercise its enforcement discretion to permit Celgene to provide to another drug manufacturer (or its agent) 500 units of Thalomid for the purpose of conducting [bioequivalency] testing, when Celgene has received confirmation in writing from the sponsor, its agent, or FDA that the sponsor of the study either has an IND in effect for the study or has otherwise provided the agency with sufficient assurance that the [bioequivalency] study will be conducted in such a manner as to ensure the safety of the subjects."

199. The FDA's letter also requested Celgene submit a supplement to its own Thalomid NDA to the same effect. Celgene failed to submit this supplement, evidencing its own disregard for safety, non-monetarily incentivized circumstances.

200. Nevertheless, Celgene's then-regulatory counsel Kerry Rothschild testified that the FDA's February 8, 2007 letter did not fully assuage Celgene's worry that a fetal exposure and birth of a baby with thalidomide-recognizable defects would have consequences to the value of Celgene's business. Celgene Chief Executive Officer, Mark Alles, testified in 2016 that of the small number of fetal exposures to Thalomid between its development and 2016, the exposures

"had minimal impact on the business as far as I know…"[74] Celgene's CEO responded to the email in a similarly unalarmed manner.

201. In a July 26, 2007, letter to Celgene, Arthur P. Bedrosian, President and CEO of Lannett, wrote:

> In order to complete our bio-study, the FDA has instructed us to purchase 250 Thalomid 200 MG Capsules from you. We kindly request information as to how to best carry out this transaction. We will be happy to supply a purchase order once you provide us with the total product cost. Submitted with this document, you will find the appropriate licenses necessary for us to purchase the product from you. We kindly ask that you inform us of any additional information you will need to complete this transaction.

202. Upon information and belief, in September 2007, Lannett faxed to Celgene's Darnell Ragland, Manager, Customer Care of Celgene, a requested copy of the February 12, 2007, FDA letter, which authorized Lannett to acquire Thalomid supplies from Celgene.

203. Celgene continued to refuse Lannett's request. Celgene even went as far as actively screening any communication from Lannett directed towards Celgene regarding requests for samples of Thalomid.

204. In a September 28, 2007, internal email (only made publicly available in redacted form in 2018), a Celgene training alert ordered employees "**DO NOT PROCESS THE ORDER**" (emphasis in original) if a generic company calls or writes requesting to order Thalomid. Instead, the call center employees were directed to log the call, advise that a management team member would return the call, and to never transfer the call to someone higher up.

205. Employees were further instructed to forward any correspondence via fax to one of their supervisors.

[74] Exhibit to MSJ Opp. at PageID 18120-21, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286.

206. Then, on October 18, 2007, Lannett wrote a letter to Mr. Ragland reiterating Lannett's request so that it could conduct bioequivalency testing needed to obtain approval to market its generic thalidomide.

207. On January 8, 2008, Celgene advised Lannett that it would not provide samples of Thalomid to Lannett. Rather, Celgene requested Lannett produce voluminous and unnecessary documentation in order for Celgene to "reconsider" the request.

208. On January 14, 2008, Lannett filed a complaint against Celgene seeking, among other things, mandatory injunctive relief requiring Celgene to provide samples of Thalomid as contemplated by the February 12, 2007, FDA letter. The complaint was dismissed without prejudice.

209. Lannett then provided all of the information that Celgene requested except its highly confidential FDA Form 483 inspection reports, which relate to the routine inspection of manufacturing facilities, given that the Thalomid samples Lannett requested would not be used for manufacturing, but rather for bioequivalency studies that it would perform overseas.

210. Lannett submitted its proposed study for FDA review and received approval on August 11, 2008.

211. Lannett refiled its complaint on August 15, 2008, alleging violations of the Sherman Act and seeking injunctive relief. Celgene filed its motion to dismiss on November 4, 2008. The motion was denied on May 13, 2010.

212. Celgene reached a confidential settlement with Lannett in 2011.

213. In its 2012 Annual Report, Lannett stated that "a sizable portion of our fiscal 2013 R&D budget is earmarked for two large market opportunity projects, C-Topical and Thalidomide." Its 2013 Annual Report stated that Lannett "successfully passed critical milestones for submitting

a product application for Thalidomide." As discussed below, Lannett eventually filed a thalidomide ANDA in late 2014.

214. Upon information and belief, the settlement between Celgene and Lannett contained anticompetitive terms, such as a promise to delay submission of the ANDA.

215. The anticompetitive effect of Celgene's conduct was to delay Lannett's ANDA. Though Lannett began requesting Thalomid samples in 2006, it was unable to obtain such samples due to Celgene's delay until after December 2011 and did not file its ANDA until 2014, at which time Celgene filed a sham patent litigation, discussed below, all to delay Lannett's thalidomide product. As of today, there is no generic thalidomide on the market.

5. Celgene Refused to Sell Samples to Dr. Reddy's.

216. Dr. Reddy's is a prescription drug manufacturer based in Telangana, India. It has been developing generic prescription drugs in the United States since 1994.

217. Dr. Reddy's requested samples of Revlimid from Celgene to perform bioequivalency testing in August 2008. Celgene did not reply to this request.

218. Dr. Reddy's repeated its request in December 2008. Celgene offered a single sentence reply in January 2009: "Celgene has no obligation to supply Dr. Reddy's with Revlimid and declines to do so."

219. In their request to Celgene, Dr. Reddy's assured Celgene any testing it performed would comply with FDA guidelines, using methods similar to Celgene's REMS program known as RevAssist to insure proper handling of the subject drugs.[75]

220. Dr. Reddy's filed a citizen petition with the FDA in June 2009, alleging that Celgene was refusing to provide samples to a generic drug manufacturer to perform bioequivalency testing.

[75] Exhibit to MSJ Opp. at PageIDs 18878-81, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 286-6.

221. Celgene once again premised its refusal on its REMS program, despite the FDA's previous guidance.

222. In 2016, Dr. Reddy's filed an ANDA for a generic lenalidomide product. As discussed below, Celgene then sued Dr. Reddy's claiming patent infringement.

6. Celgene Refused to Sell Samples to Teva.

223. Teva requested a total of 5,000 Capsules in 5, 10, 15, and 25 mg dosages of Revlimid from Celgene to perform bioequivalency testing in March 2009.

224. In their letter to Celgene, Teva stated that its "procedures for conducting any required testing involving lenalidomide and the Revlimid drug product provided by Celgene Corporation will fully comply with FDA requirements. Teva's controls with respect to lenalidomide with be comparable to the RevAssist program."

225. In April of 2009, Celgene responded to Teva's request, and in a one sentence reply, stated "[t]his letter is to inform you that your request for 5,000 capsules of REVLIMID (lenalidomide) in varying strengths is declined."

226. Celgene's refusal to provide Teva with samples of Revlimid follows a similar course of conduct with other generic pharmaceutical companies.

7. Celgene Refused to Sell Samples to Watson.

227. In June of 2009, much like the other generic manufacturers described above, Watson contacted Celgene to acquire samples of Thalomid and Revlimid for bioequivalency testing.

228. In its request, Watson assured Celgene the process by which it would handle the samples of these drugs would fully comply with a restricted distribution system similar to RevAssist.

229. Furthermore, Watson assured Celgene that FDA guidelines would be followed, and no drug would be distributed in violation of these guidelines, which would be unlikely to happen given Watson's experience and expertise in the generic drug manufacturing market.

230. In July 2009, despite Watson's assurances that the requested samples would be handled in a safe, effective, and FDA-compliant manner, Celgene responded with a list of 10 pieces of evidence and documentation Watson would need to provide before Celgene would consider Watson's request. Celgene indicated it would respond to Watson's request for Revlimid in a separate letter.

231. Tellingly, Celgene did not say satisfying these 10 requirements would facilitate a prompt sale of the samples, merely that at that time Celgene would "consider" it.

232. Upon information and belief, like the generic manufacturers before and after, Watson was unable to obtain the samples of Thalomid and Revlimid it requested, with no logical reason provided.

8. Celgene Refused to Sell Samples to Sandoz.

233. In May of 2012, much like the other generic manufacturers described above, Sandoz contacted Celgene attempting to acquire samples of Thalomid and Revlimid for bioequivalency testing.

234. In response, Celgene refused to provide the samples, and instead listed nine prerequisites Sandoz had to satisfy before it would consider selling the requested samples.

235. These prerequisites included Sandoz provide "Proof of liability insurance sufficient to cover events associated with thalidomide and lenalidomide", "[p]olicies for biohazard handling, disaster recovery plans as well as the storage and use of teratogenic products", and "[w]ritten confirmation that an IND is in effect or a study protocol . . . has been approved by the FDA."

236. Like its correspondence with other generic manufacturers wishing to obtain drug samples, Celgene referenced the REMS procedures as a reason it could not immediately supply Sandoz with samples, despite FDA approval of Sandoz's procedures.

237. Upon information and belief, like the generic manufacturers before it, Sandoz was unable to obtain the samples of Thalomid and Revlimid it requested.

238. Celgene has provided Revlimid and/or Thalomid to no generic manufacturer.

9. Celgene Prevented Barr from obtaining API Supply from Seratec.

239. After the FDA approved Celgene's Thalomid, Barr, a generic drug manufacturer, sought to develop a generic version of thalidomide. As discussed, to market a generic drug, FDA requires a generic manufacturer to file an ANDA application detailing the proposed drug. The ANDA filer must identify its API supplier in its application. The API supplier must submit a Drug Master File ("DMF") to the FDA, which is evaluated with the ANDA.

240. In approximately 2004, Barr succeeded in procuring thalidomide API from Seratec S.A.R.L. ("Seratec"), a French supplier, to develop a generic version of Thalomid by September 2005. Barr submitted its ANDA to the FDA and was waiting to receive a DMF letter from Seratec.

241. Barr's ANDA proposed a skinny label, only seeking approval for ENL, and not MM.

242. While Barr and Seratec were finalizing negotiations, Celgene and Seratec entered an exclusive supply agreement for thalidomide. Upon information and belief, Celgene demanded exclusivity from Seratec to interfere with Barr's ability to market generic Thalomid. The exclusivity agreement was not because Celgene required all the API that Seratec could produce. Seratec, therefore, could no longer supply Barr with its thalidomide API. The FDA did not accept

Barr's ANDA due to deficiencies in providing a DMF from Seratec.[76]

243. Consequently, Barr was forced to find a different thalidomide supplier and repeat testing, causing it great expense and delay in launching generic thalidomide.

244. On February 27, 2006, Celgene's competitive intelligence firm, GBMC, updated Celgene that Barr completed bioequivalency testing and was planning on filing a thalidomide ANDA in the second quarter of 2006 using API from either Antibioticos of Italy or Shilpa of India. GBMC noted that "[t]hese companies were being used to replace the Seratec API that Barr originally was using for its ANDA."

245. After securing a new supplier and performing new bioequivalency studies and validation testing, Barr submitted its thalidomide ANDA on September 22, 2006. The ANDA showed that Barr's generic product was bioequivalent to Celgene's Thalomid. The FDA accepted Barr's thalidomide ANDA for filing on December 4, 2006.

246. Celgene subsequently initiated a patent infringement lawsuit against Barr for its thalidomide ANDA, as discussed more thoroughly below, initiating an automatic 30-month stay of FDA's approval of Barr's ANDA.

247. GBMC predicted that Barr could be expected to receive FDA approval of its thalidomide ANDA in the first quarter of 2009.

248. In a May 2009 email between executives at Celgene, which contained the minutes of a previously held internal meeting, these executives discussed Barr's attempt to market generic

[76] It was unclear to Celgene how Barr acquired Thalomid samples for bioequivalency testing in 2005. In Celgene's response to interrogatories in a separate litigation recently made public, Celgene noted "Celgene informed the FDA of its belief that Barr had acquired Thalomid capsules from a pharmacy in Astoria, New York in violation of the requirements of the S.T.E.P.S. program. The FDA informed Celgene that it did not intend to 'recapture' these capsules from Barr, and that the manner in which Barr obtained Thalomid for use in its bioequivalency testing would not affect FDA's consideration of any subsequent ANDA with respect to thalidomide that Barr might file."

thalidomide in the USA.[77]

249. According to the minutes of the meeting: "Dianne Azzarello, Regulatory Canada discussed possible ways to defend Thalidomide against generic infiltration in the USA. From her experience in working with generic drug providers, she is of the opinion that we are able to use bioequivalence as generic defense strategy. The team supports this notion. If generic companies have to effectively prove that they are at least equivalent to what Celgene has to offer (incl. Celgene's RiskMAP) before making product available on the market."

250. They also discussed paying for research and publishing research papers stating generic manufacturers' version of Thalomid were not bioequivalent: "Diane Azzarello and Henry Lau are working with Dr. Iain McGilveray who will publish a paper providing evidence that many other formulations of thalidomide available are not bio equivalent to Celgene's Thalomid. We may also include our simple formulation and its chemical properties as rationale. Funding for this publication is estimated to be $40k $60k."

251. These internal discussions are further evidence Celgene was not negotiating the sale of sample drugs to generic manufacturers in good faith and were instead employing delay tactics at every turn to resist supplying generic manufacturers with the requested drugs.

ii. Celgene Had No Legitimate Business Justifications for Refusing Samples to Would Be Competitors Because Its Safety Concerns Were Pretextual.

252. While Celgene refused to supply any potential ANDA sponsor the necessary and required samples of Revlimid and/or Thalomid based on pretextual safety concerns, it authorized its competitive intelligence firm to purchase, handle, and transfer thalidomide with no safety training required.

[77] Exhibit to Brief in Further Support of Motion for Summary Judgment at PageIDs 16101-4, *Mylan Pharmaceuticals, Inc. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Mar. 20, 2018) ECF No. 284-4 ("MSJ Reply Papers").

253. In 2003, Celgene authorized GBMC to purchase thalidomide API from a European supplier, Alan Pharmaceuticals. In fact, GBMC was authorized by Celgene to use undercover purchases to obtain samples of thalidomide API from various API suppliers. In an undated letter, GBMC detailed the sequence of events it used to acquire, at Celgene's request, thalidomide samples outside the normal chains of distribution. This sequence included falsifying prescriber names and permitting GBMC (a non-pharmaceutical company with no experience in handling teratogenic drug product) to handle thalidomide samples, all without a formal tracking mechanism. Celgene's Senior Director of Market Research testified in a previous litigation that he did not notify Celgene's legal department of these undercover purchases, that Celgene did not do background checks on individuals that would be handling the drug product, and that he could not recall whether the purchased product was in its proper packaging when Celgene received it, or who at Celgene received it.

254. The Celgene-authorized transactions did not comport with any safety protocol.

255. Celgene willingly and frequently provided access to Thalomid and Revlimid to non-competitor research organizations, outside the REMS process and without FDA guidance or approval for the safe handling of the drug products, for the purpose of conducting clinical studies.

256. Celgene provided Revlimid for at least 3,600 different research and investigational studies that all operated outside the REMS process. Celgene similarly provided Thalomid for over 100 investigator-initiated trials ("IIT").[78]

257. For example, Celgene provided Thalomid and Revlimid to the Johns Hopkins School of Medicine for clinical trials and provided Revlimid to Intergroupe Francophone du Myelome, University Hospital of Toulouse, and Groupe Francophone Des Myelodysplasies, as

[78] IITs are clinical studies initiated and managed by non-pharmaceutical company researchers, such as individual investigators, institutions, collaborative study groups, cohorts or physicians.

well as the National Cancer Institute, Eastern Cooperative Oncology Group, Mayo Clinic, and MD Anderson Cancer Center in Houston, Texas.

258. An IIT process is initiated when an investigator submits a Letter of Intent ("LOI") outlining a proposal. The brand company, here Celgene, then reviews the proposal. Celgene testified that it tried not to review the full protocol, but rather would typically review a simplified synopsis, along with the nature of the request, the budget, and the amount of drug requested. The request, typically adjudicated within two months, does not require in-house counsel assistance. Celgene has never denied an IIT proposal due to fetal exposure safety concerns.

259. After approving an IIT proposal, Celgene works with the investigator to draft a study protocol and consent form which then is submitted to the FDA for approval. Celgene had admitted that FDA's approval gives Celgene confidence in the safety of the trial. Celgene then supplies Revlimid or Thalomid to the investigator to initiate the study.

e. Celgene Commits Fraud on the USPTO and Files Sham Litigations Seeking to Enforce its Fraudulently Obtained Patents.

260. Even when a generic manufacturer managed to obtain a sample of Thalomid or Revlimid, Celgene was still able to unlawfully block them from the market by obtaining numerous redundant patents related to the composition, and plans for safe distribution, of Thalomid and Revlimid. Celgene's construction of a patent fortress was part of its multifaceted and decades-long scheme to monopolize the markets for Thalomid and Revlimid.

261. These types of patents generally claim the use of registries to register patients, prescribers, and pharmacies, testing and regular re-testing the patient for signs of harmful side effects associated with the drug (including pregnancy testing), counseling patients about the risks associated with the drug, limiting the dispensed amount of the drug, and prescribing and dispensing the drug after analyzing the risk and determining that it is acceptable.

262. The patent on Celgene's active ingredient in Revlimid, the '517 Patent, expired in 2019. The last of Revlimid's patents listed in the Orange Book, the '800 Polymorph patent, expires in 2028.

263. Celgene, armed with its fraudulent patents, serially filed sham patent infringement lawsuits and citizen petitions against any Paragraph IV ANDA filer. Through these serial sham litigations, Celgene was able to successfully, and illegally, block generic entrants from the Revlimid and Thalomid markets.

i. Celgene's Fraudulent Patent Prosecution.

264. The original, core patent for the composition of Celgene's thalidomide-derived drugs is the '517 Patent, filed in 1996. Thalidomide, the drug on which Revlimid is based, was first on the market in 1957. The innovations on which the '517 Patent is based are obvious in light of the innovations and research conducted long before Celgene began its effort to bring Thalomid and Revlimid to market; thus, the '517 Patent and the subsequent patents derived from it are invalid.

265. Thalidomide was found to be immunotherapeutic in the 1960's, meaning it was known that thalidomide could treat diseases by inducing, enhancing or suppressing an immune response. Extensive scientific literature establishes the immunomodulatory properties of thalidomide and its derivative, lenalidomide, the active ingredient in Revlimid. It was well established that thalidomide has immunomodulatory properties, that thalidomide derivatives have the same immunomodulatory properties as thalidomide, that thalidomide was effective in the treatment of autoimmune diseases, that thalidomide derivatives inhibited Tumor Necrosis Factor Alpha, and that thalidomide is an angiogenesis inhibitor which also aids in the treatment of multiple myeloma. There has been nothing unexpected or unanticipated about the effects or uses of Thalomid or Revlimid over the precedent scientific literature. In filing the '517 Patent with the

USPTO, none of these precedents were cited by Celgene. The USPTO examiners were not aware of key prior art when the '517 Patent was granted.

266. In 2003, Celgene filed the '012 Patent for thalidomide, a drug that had first been used almost half a century prior. Again, none of the relevant precedent above was cited in the USPTO filing by Celgene. Under 37 CFR 1.56, Celgene had a duty to disclose information material to patentability. Patents will be revoked, and applications will be denied if this duty of disclosure was violated through bad faith or intentional misconduct. For the drug composition patents, as well as the distribution patents discussed below, Celgene has shown a pattern of omitting important precedents in USPTO filings for Thalomid and Revlimid.

1. Celgene Tried to Extend its Monopoly by Filing Redundant Drug Composition Patents Based on Previously Ill-Gotten Patents.

267. In an effort to extend their monopoly on the sale of thalidomide derivatives, Celgene began filing additional patents on the polymorphic forms of lenalidomide. Polymorphs, also known as solvates or crystalline forms, of previously patented compounds are routinely developed as a standard practice in the pharmaceutical industry, according to a US patent examiner in a rejection of one of Celgene's polymorph patent applications, and generally not separately patentable.

268. However, Celgene managed to get the Polymorphs patents approved by the USPTO and filed in the FDA Orange Book, the '800 Patent and the '217 Patent, which expire in 2027 and 2024, respectively. Since these patents have the latest expiration dates of any patents associated with Thalomid or Revlimid, they have been key patents cited in repeated attempts by Celgene to block generic competitors from the market. Celgene routinely cites these Polymorph patents against generic manufacturers that have filed generic Thalomid and/or Revlimid ANDAs.

269. In doing so, Celgene has also repeatedly left open the Polymorph patents to charges of invalidity and has repeatedly settled instead of testing the strength of these patents in court for fear of the result. When Natco Pharma Limited ("Natco Pharma") filed an ANDA for its generic version of lenalidomide, Celgene brought suit against it, Watson, and Arrow International Ltd. ("Arrow") (collectively, "Natco"), claiming infringement. The parties agreed to a Markman hearing to settle the meaning of disputed terms in the patent. Citing Celgene's own clarified definition of the term "hemihydrate," Natco amended its invalidity contentions to the '800 patent, arguing that that it was invalid for indefiniteness, lack of enablement and lack of written description. When Celgene was unable to prevent Natco from raising these amended invalidity contentions, Celgene quickly settled with Natco, allowing Natco market share prior to the expiration of the patents rather than let its Polymorph patents face invalidation. Having learned a dangerous lesson, Celgene did what was necessary to avoid a similar Markman hearing over the meaning of "crystalline" in its subsequent litigation against Dr. Reddy's. [79]

270. Celgene knows that the overbroad terms of its redundant Polymorph patents are an attempt to block generic competitors from bringing non-infringing products to market where the generic manufacturer has developed a suitable workaround to Celgene's patents. The claims of Celgene's other Polymorph patent, the '217 Patent, also call out crystalline and hemihydrate forms, and are invalid for the same reasons as the '800 patent. These patents, like the '517 Patent from which they were derived, were obtained due to a failure to disclose publicly available prior art and research from decades earlier, which anticipate and invalidate the patent. Celgene's failure provides an independent basis for invalidity. These polymorphs are also obvious variants of the

[79] Letter to Court, *Celgene Corp. v. Dr. Reddy's Laboratories Ltd.*, 2:16-cv-7704 (D.N.J. Mar. 23, 2018) ECF No. 77 (On the date that its responsive Markman pleadings were due, Celgene filed a letter informing the court that it resolved its claim construction disputes with Dr. Reddy's and would not be filing responsive pleadings).

composition of matter patent, adding further basis for invalidity. Finally, based on Celgene's own representations in the Markman hearing that was held in the *Natco* litigation, the claims of the patent are unenforceable as overbroad.

271. The anticompetitive effect of Celgene's conduct with respect to the composition patents was to erect a fortress of protection for Celgene's continued monopoly.

2. Celgene Failed to Disclose Material Information on Patentability of The Distribution Method Patents.

272. As discussed above, in 1998, Celgene only listed the '501 Patent in the Orange Book in connection with Thalomid. Since then, it has listed numerous additional patents, including the '720, '976, '977, and '784 patents (together with the '501 Patent, the "Distribution Method Patents") in the Orange Book in connection with Thalomid.

273. The '501 and '720 patents were invalidated by the Patent Trial and Appeal Board ("PTAB") on October 26, 2016.[80]

274. The PTAB found the '501 Patent invalid as obvious over the combined disclosures of three asserted prior art references as representative of the level of ordinary skill in the art.

275. Guidance regarding the clinical use and dispensing of thalidomide was provided by an existing publication in 1994 that identified a patient subpopulation of women who could and wished to become pregnant, warning that they should not be treated with Thalomid, and recommending counseling on the risks of thalidomide as well as the use of contraception.[81]

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[80] See *Coalition for Affordable Drugs VI LLC, et al., v. Celgene Corp.,* IPR2015-01092, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01092; IPR2015-01096, Paper No. 73 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01096; IPR2015-01102, Paper No. 75 (P.T.A.B. Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01102; IPR2015-01103, Paper No. 76 (Oct. 26, 2016), https://portal.unifiedpatents.com/ptab/case/IPR2015-01103 ("*Coalition*").

[81] R.J. Powell and J.M.M Gardner–Medwin, *Guideline for the clinical use and dispensing of thalidomide*, POSTGRAD MED. J. 70, 901–904 (1994) ("Powell").

276. Further guidance was also provided by the existing pregnancy-prevention program for women users of Accutane, a Vitamin A analogue of isotretinoin and a known teratogenic drug. Accutane was subject to a program of preventative measures, such as pregnancy-risk warnings on packaging, targeting of women of childbearing age for the pregnancy-prevention program, and communication between physicians and patients regarding the drug's teratogenic risk and the need to prevent pregnancy.[82]

277. Guidance for the use of a national database to register prescribers, pharmacies, and patients as a way to restrict access to drugs that could be potentially hazardous was also published well before the '501 Patent was filed, such as the nation-wide registry for patients requiring clozapine, a potent anti-psychotic drug with potential for serious side effects.[83]

278. The PTAB found that a person of ordinary skill in the art would have understood how to implement Powell's teachings in clinical and pharmacy settings in view of the Accutane Pregnancy Prevention Program and the Clozaril (clozapine) controlled distribution model outlined in Dishman. The PTAB was not persuaded by Celgene's argument that the prior art did not specifically single out men who could impregnate a woman as a subgroup, noting that a skilled artisan would have recognized that the sperm of male patients could be damaged by teratogenic drugs and consequently result in birth defects if the male was to impregnate a female.[84]

279. The PTAB found the '720 Patent invalid as obvious over the combined disclosures cited against the '501 Patent for the original S.T.E.P.S. program, while finding that the inherent dangers of Thalidomide would drive someone of ordinary skill in the art to proactively improve

[82] Allen A. Mitchell et al., *A Pregnancy–Prevention Program in Women of Childbearing Age Receiving Isotretinoin*, NEW ENG. J. MED. 333:2, 101–06 (Jul. 13, 1995) ("Mitchell").
[83] Benjamin R. Dishman et al., *Pharmacists' role in clozapine therapy at a Veterans Affairs medical center*, AM. J. HOSP. PHARM. 51, 899–901 (Apr. 1, 1994) ("Dishman").
[84] *Coalition,* IPR2015–01092, Paper No. 73.

the system. Citing U.S. Patent No. 5,832,449 (issued Nov. 3, 1998, "Cunningham"), which describes an approval code used by prescribers and pharmacies to track and manage pharmaceutical products, the PTAB found that a person of ordinary skill in the art could predict that such an approval code could be utilized by prescribers and pharmacies to track and manage Thalomid and Revlimid. In light of this prior art, the PTAB invalidated the '720 patent as obvious.

280. As the PTAB noted, "[w]hen it benefitted [Celgene's] interests before the FDA, [Celgene] freely admitted that its 'plan [for thalidomide] is built on experience with restrictions on such other drugs with severe adverse effects as Accutane … and Clozaril." Before the USPTO however, Celgene repeatedly failed to disclose the very materials that it relied on in presenting its program to the FDA, along with other similar prior art such as the Clozaril Patient Monitoring Service and numerous published works describing the features of REMS programs similar to Celgene's original and modified S.T.E.P.S. programs.

281. On July 30, 2019, the Federal Circuit affirmed the findings of the PTAB invalidating the '501 and '720 patents for obviousness.

282. The '976 Patent, the '977 Patent, and the '784 patent, filed more than three years later, are nearly identical to the invalidated '501 and '720 patents. In fact, many of these patents were so similar that Celgene did not even bother changing the title or abstract describing the patent.

283. Celgene also listed the '886 Patent in the Orange Book in connection with Thalomid on November 20, 2012.

284. Celgene listed each of these patents in the Orange Book for both Thalomid, and later Revlimid, with full knowledge that protocols for the safe distribution of dangerous drugs like Thalomid and Revlimid have been in public use for years before Celgene filed any of its patent applications.

285. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud and are unenforceable. Celgene caused these patents to be listed in the Orange Book with knowledge that they were fraudulently obtained and are unenforceable. Celgene's withholding of material information on patentability with the intent to deceive the USPTO was done for the anticompetitive purpose of excluding generic competitors by erecting artificial barriers of entry, thus maintaining a market monopoly.

286. The public prior use and/or publication of Celgene's claimed "Distribution Method" inventions include:

a. The Clorazil Patient Monitoring Service ("CPMS")

287. The CPMS is a program for the distribution of Clorazil™. Clorazil is used to treat individuals with schizophrenia. A major side effect of Clorazil is agranulocytosis, a potentially fatal blood disorder.

288. Clorazil is distributed through the CPMS, which uses a national registry for patients, prescribers, and pharmacies. This registry identifies and reduces the risk of Clorazil-related complications.

289. The CPMS uses a computerized registry that includes patient information such as white blood cell counts to determine risk factors. The CPMS also tests white blood cell counts prior to starting Clorazil therapy. The CPMS mandates prescribing and dispensing only a limited supply of Clorazil after the prescriber determines that the risk is acceptable and provides the dispensing pharmacy with a report containing white blood cell counts and the doctor's opinion that the patient is eligible to receive required Clorazil. Additionally, the CPMS contains protocols for discontinuing treatment if the doctor determines, based on weekly blood tests, that the risk becomes unacceptable. Weekly refills are only provided after the same criteria for the initial dispensation are met again at the start of each week.

290. The CPMS qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one year before the earliest priority date of the Distribution Method Patents and the '886 Patent.

291. The applicants of those patents, their agents, and/or their attorneys did not disclose the CPMS to the USPTO during pendency of the applications from which the Distribution Method Patents issued.

b. Honigfeld, "Effects of the Clozapine National Registry System on Incidence of Deaths Related to Agranulocytosis," *Psychiatric Services*, 47(1):52-56 (1996) ("Honigfeld I")

292. Honigfeld I describes details of the CPMS and qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was publicly available and accessible more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

293. The applicants, their agents, and/or their attorneys did not disclose the Honigfeld I to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

c. Honigfeld, *et al*., "Reducing Clozapine-Related Morbidity and Mortality: 5 Years of Experience with the Clozaril National Registry," J. *Clin. Psychiatry* 59 (suppl 3): 3-7 (1998) ("Honigfeld II")

294. Honigfeld II also details the protocols of the CPMS and qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available information prior to the earliest priority date of the '501 and '976 patents. Honigfeld II qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. § 102(b), because it was publicly available

information more than one year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

295. The applicants, their agents, and/or their attorneys did not disclose Honigfeld II to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

d. The "Guide to the Clozaril Patient Monitoring Service," Novartis Pharmaceuticals UK Ltd. (Nov. 1997) ("The Guide")

296. Details of the CPMS are described in the Guide, which qualifies as prior art to the '501 and '976 patents under 35 U.S.C. § 102(a) because it was publicly available prior to the earliest priority date of the '501 and '976 patents. The Guide qualifies as prior art to the '720, '977, '784, and '886 patents under 35 U.S.C. §102(b), because it was publicly available more than one year prior to the earliest priority date of the '720, '977, '784, and '886 patents.

297. The applicants, their agents, and/or their attorneys did not disclose the Guide to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

e. The ACCUTANE Pregnancy Prevention Program ("PPP")

298. The PPP is a program for the distribution of Accutane, known generically as isotretinoin. The PPP was developed and implemented to prevent fetal exposure to isotretinoin. The PPP included an information package for physicians warning of the risks of dispensing the drug to pregnant women, a patient informed consent form containing warnings detailing the risks associated with Accutane and the requirements to receive Accutane and required pregnancy testing and birth control counseling before the patient started a course of Accutane therapy. It also required a patient survey on compliance.

299. The PPP qualifies as prior art to the claims of the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was commercially used in the United States more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent.

300. The applicants, their agents, and/or their attorneys did not disclose the PPP to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

f. The Accutane PPP Package, a 1994 patent and prescriber information package for Accutane, distributed by Roche Pharmaceuticals ("PPP Package")

301. The PPP Package described details of the PPP. It qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b), because it was publicly available more than one year prior to the earliest priority date of the Distribution Method Parents and the '886 Patent.

302. The applicants, their agents, and/or their attorneys did not disclose the PPP Package to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

g. A Centers for Disease Control public meeting entitled "Preventing Birth Defects Due to Thalidomide Exposure" and transcript from March 26, 1997 "The CDC Meeting and Transcript"

303. On March 26, 1997, the CDC held a public meeting to discuss thalidomide and its associated risks. The meeting was attended by at least two Celgene employees: Dr. Jerome Zeldis, the then Vice President of Medical Affairs at Celgene, and Mr. Bruce A. Williams, a named inventor for the Distribution Method Patents and the '886 Patent.

304. The transcript of the CDC Meeting shows that the PPP and the CPMS were discussed, as was the use of the protocols in those two systems in designing a similar protocol for thalidomide.

305. The CDC Meeting attendees discussed potential elements to be part of a thalidomide distribution program, including: (1) patient, pharmacy, and prescriber registration; (2) counseling patients about the risks of thalidomide and the need for contraception; (3) required pregnancy testing before thalidomide is prescribed; (4) monthly testing thereafter; (5) providing proof that the patient is not pregnant before the drug can be dispensed and providing contraceptives with the drug; (6) limiting the length of the prescription to a monthly supply; and (7) requiring return to the prescriber before refilling the prescription.

306. The CDC Transcript was publicly available under the Freedom of Information Act more than one year prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. It therefore qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(b).

307. The applicants, their agents, and/or their attorneys did not disclose the CDC Meeting or the CDC Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents and the '886 Patent issued.

h. Zeldis, *et al*., "S.T.E.P.S.™: A Comprehensive Program for Controlling and Monitoring Access to Thalidomide," *Clinical Therapeutics* 21(2): 319-30 (1999) ("Zeldis")

308. Zeldis qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. §102(b), because it was publicly available more than one year prior to the earliest priority date of the '720, '977, and '784 patents.

309. Zeldis is co-authored by Celgene employees, including Zeldis and named inventor Williams. It described the S.T.E.P.S. program developed by Celgene, with the guidance

of the FDA, to monitor and control access to thalidomide. Zeldis states that the S.T.E.P.S. protocol is "based in part on experience gained with other drugs—specifically isotretinoin and clozapine— that offer important clinical benefits but carry the potential for serious harm."

310. Zeldis states:

> Celgene has incorporated elements of both these successful programs into the S.T.E.P.S.™ program for controlling the distribution of thalidomide. Educational materials for patients and physicians and label warnings similar to those used in the isotretinoin program are coupled with clinician and patient registration and testing similar to those used in the clozapine program.

311. Zeldis cites Honigfeld I and Honigfeld II in its discussion of Clorazil.

312. The applicants, their agents, and/or their attorneys did not disclose Zeldis to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

i. The September 4 and 5, 1997 Center for Drug Evaluation and Research of the Food and Drug Administration public meeting ("The CDER Meeting and Transcript").

313. The September 4-5, 1997, CDER Meeting was recorded in a publicly available transcript and at least seven Celgene employees, including named inventor Bruce Williams who made a presentation on preventing fetal exposure to thalidomide, attended the meeting.

314. Williams stated:

> [W]e recognize that there may be some models in the marketplace today which could serve as at least a starting point in our thinking as we develop this program. Two of them came to mind that I would like to just speak very briefly to, to indicate why we feel that they are relevant models, but also where we feel they may not go far enough for this particular circumstance. The first is one that this committee, particularly, is very familiar with. And that is Roche's Accutane, used to treat severe acne, and known to be a human teratogen.

315. Williams described the Accutane system, the PPP, and its purported drawbacks, which he described as a lack of a mandatory registry and an inability for a pharmacist to determine at dispensing whether the patient has participated in Roche's program.

316. He noted that the PPP's purported drawbacks drove Celgene to analyze the CPMS protocol, to which he stated:

> In looking at how Sandoz structured this [Clozaril] system, we began to see that by taking elements from the Roche program [Accutane], elements from the Clozaril program and other unique elements, we would create a system that really would be state of the art, represent a significant step, we believe, forward in the ability to make drugs like thalidomide available to patients who need it, while at the same time providing a very high margin for protection.

317. The CDER Transcript qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act prior to the earliest priority date of the Distribution Method Patents and the '886 Patent. The CDER Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available information under the Freedom of Information Act more than one year prior to the earliest priority date of the '720, '977, and '784 patents.

318. The applicants, their agents, and/or their attorneys did not disclose the CDER Transcript to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

j. The September 9 and 10, 1997 public workshop held by the National Institutes of Health, FDA, and CDC, entitled "Thalidomide: Potential Benefits and Risks, Open Public Scientific Workshop" ("The NIH Meeting and Transcript").

319. The NIH Meeting on September 9-10, 1997 was recorded in a publicly available transcript. There, the named inventor *Williams gave a presentation regarding a Celgene proposal* "for a distribution and education system" for thalidomide.

320. Williams stated:

> *When we started in this endeavor we looked to see what else was in the marketplace that might serve as a model*. We accepted that we were unlikely to find any single model that carried all of the elements that would likely be necessary for this drug, but *we did find two that in part covered many of the elements that might be required*. Accutane, we heard about yesterday. Comprehensive educational program, counseling, and good contraception, informed consent, a package with integrated product warnings, and a surveillance system, albeit voluntary. Many elements that clearly with either change or updating or enhancement would likely be relevant to what needed to be done for thalidomide. We also heard about the Novartis program for Clozaril, a drug used to treat schizophrenia and introduced in an era where existing antischizophrenia drugs were not particularly effective for many patients. In addition, they carried their own baggage of side effects. However, in a small proportion of patients who take this drug, a granular cytosis [sic] can develop in a very short period of time.

321. The NIH Transcript qualifies as prior art to the Distribution Method Patents and the '886 Patent under 35 U.S.C. § 102(a), because it was publicly available under the Freedom of Information Act before the earliest priority date of the Distribution Method Patents and the '886 Patent. The NIH Transcript also qualifies as prior art to the '720, '977, and '784 patents under 35 U.S.C. § 102(b), because it was publicly available and accessible under the Freedom of Information Act more than one year prior to the earliest priority date of the '720, '977, and '784 patents.

322. The applicants, their agents, and/or their attorneys did not disclose the NIH Meeting or Williams' presentation at the NIH Meeting to the USPTO during the pendency of the applications from which the Distribution Method Patents issued.

323. Each of the above enumerated publications, meetings, or programs constitutes prior art that Celgene was required to disclose but failed to disclose to the USPTO, for each of the Distribution Method Patents.

324. In its 2010 application for the '886 Patent, Celgene failed to disclose the existence of the PPP Package or the CDC Transcript. Had Celgene disclosed the PPP Package or the CDC Transcript, the USPTO would not have issued Celgene the '886 Patent.

k. The Distribution Method Patents are Unenforceable.

325. All the above prior arts are material to the patentability of the Distribution Method Patents. They firmly establish, *prima facie*, unpatentability under 35 U.S.C. §§ 102 and 103. Each prior art listed is material to the patentability of the Distribution Method Patents because, but for Celgene's failure to disclose them, the USPTO would not have allowed any or all of the claims of the Distribution Method Patents to issue.

326. All the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they contradict or are inconsistent with positions the applicants took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability.

327. All of the above prior arts are material to the patentability of the Distribution Method Patents because, individually and/or taken together, they constitute information that a reasonable Examiner reviewing the applications would consider material in determining whether to allow the proposed claims to issue.

328. The applicants of the Distribution Method Patents, their agents, and/or their attorneys and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method

Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

329. During the pendency of the applications from which the Distribution Method Patents issued, the applicants, their agents, attorneys, and anyone else substantively involved in the application, owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the Distribution Method Patents issued. Pursuant to that duty, they were required to disclose all information material to the applications from which the Distribution Method Patents issued.

330. While the applications from which the Distribution Method Patents issued were pending, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the above listed prior arts and knew that they were material to those applications.

331. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution withheld the above listed prior arts with the intent to deceive the Patent Examiner.

332. The Distribution Method Patents applicants, their agents, attorneys, and anyone else substantively involved in the prosecution knowingly and willfully misrepresented and omitted material information during the pendency of the applications from which the Distribution Method Patents issued. But for these misrepresentations and omissions, the Distribution Method Patents would not have issued.

333. The Distribution Method Patents were obtained from the USPTO through knowing and willful fraud; accordingly, they are unenforceable.

334. The Supreme Court's decision in *Alice Corp. v. CLS Bank International*,[85] after the distribution method patents were issued, has raised doubts that REMS patents are even patentable subject matter at all. In its decision, the Court created a new test for patents that are directed to abstract ideas, such as a strategy for distribution, in which the court will examine the elements of the claim to determine whether it contains an 'inventive concept' that is enough to 'transform' the abstract idea in the claims enough to make it eligible for patent protection. Simply performing a process that has been done before, such as safely dispersing prescriptions, and performing it on a computer does not transform an abstract idea into patentable subject matter. Since *Alice,* patents for REMS distribution methods have been invalidated as unpatentable abstract ideas. [86]

335. Celgene caused the Distribution Method Patents to be listed in the Orange Book with knowledge that they were fraudulently obtained from the USPTO and are unenforceable. Celgene listed the Distribution Method Patents in the Orange Book with the intent and purpose of impeding thalidomide and lenalidomide ANDA filings and delaying FDA approval of any ANDAs for at least 30 months pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

l. Celgene Tried to Extend Its Monopoly by Filing Redundant Distribution Method Patents Based on its Previously Ill-Gotten Patents.

336. Celgene applied for another patent, the '886 Patent, on December 13, 2010, just after Barr and Natco each filed an ANDA for thalidomide. Celgene's patent application did not disclose the PPP Package or the CDC Transcript as prior art.

337. Both the PPP Package and the CDC Transcript are material to the patentability of the '886 Patent. These two prior arts contradict or are inconsistent with positions the applicants

[85] *Alice Corp. Pty. Ltd. v. CLS Bank Intern*., 573 U.S. (2014).
[86] *See Par Pharmaceutical, Inc., et al., v. Jazz Pharmaceuticals, Inc.,* IPR2015-00554, Paper No. 68 (P.T.A.B. July 27, 2016) for patent 7,668,730 previously held by Jazz Pharmaceuticals, https://portal.unifiedpatents.com/ptab/case/IPR2015-00554.

took in opposing arguments of unpatentability relied on by the USPTO or asserting arguments of patentability. They are also material because they constitute information that a reasonable Examiner would consider important in deciding whether to allow the proposed claims of the '886 Patent to issue. Had the USPTO been aware of those undisclosed prior art references, the USPTO would not have allowed any or all of the claims of the '886 Patent to issue.

338. Celgene obtained the '886 Patent on November 20, 2012, through knowing and willful fraud. It is therefore unenforceable. Celgene further caused the '886 Patent to be listed in the Orange Book with knowledge that it was fraudulently obtained from the USPTO and is unenforceable. Celgene acted with the intent to thwart or otherwise discourage generic manufacturers from filing thalidomide and/or lenalidomide ANDAs, and to delay FDA approval of any such ANDA for at least 30 months pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

339. The applicants of the '886 Patent, their agents, attorneys, and anyone else substantively involved in the prosecution owed a duty of good faith and candor to the USPTO during the pendency of the applications from which the '886 Patent issued. As part of that duty of candor, they were required to disclose information material to the application from which the '886 Patent issued.

340. During the pendency of the application from which the '886 Patent issued, the applicants, their agents, attorneys, and anyone else substantively involved in the prosecution were aware of the PPP Package and the CDC Transcript, knew that that these two prior arts were material to that application and withheld them with the intent to deceive the Patent Examiner. But for these omissions and misstatements, the '886 Patent would not have issued.

m. Celgene Attempted to Extend Its Monopoly by Filing Redundant Dosing Patents and Failed to Disclose Material Information on Patentability of the '745 Patent.

341. Celgene filed the '745 Patent for methods and compositions for inhibition of angiogenesis in 2006, listing Robert D'Amato as inventor. D'Amato had filed and was granted the 5,593,990 (the "'990 Patent") patent for methods and compositions for inhibition of angiogenesis in 1995, along with several other patents relating to thalidomide analogs, based on his research with The Children's Medical Center Corporation ("CMCC") in Boston. Around this same time, Celgene was beginning to file its initial patents for thalidomide analogs, which resulted in Celgene and the company to whom CMCC had licensed its patents, EntreMed, suing each other for infringement and challenging the validity of the other's patents. This dispute was resolved in 2002 when the parties entered into an exclusive licensing agreement allowing Celgene a worldwide, exclusive license in CMCC's entire portfolio of thalidomide analog patents in exchange for paying royalties.

342. When Celgene filed for the '745 Patent, it did not cite the '990 Patent or any of the other D'Amato dosing patents that they held the exclusive license for that dealt with treating disease states resulting from angiogenesis. The addition that anti-inflammatory drugs and NSAIDS can inhibit angiogenesis alone or in combination with thalidomide and its analogs was already disclosed by prior art. Celgene filed this redundant patent in an attempt not only to extend its monopoly but to do so in a way to not have to continue to pay royalties to CMCC. Though its attempts to maintain patent protection without paying the accompanying royalties were unsuccessful, Celgene was able to leverage the unenforceable and invalid '745 Patent, as well as the additional invalid dosage patents, in its sham litigation with Lannett, as discussed below.

ii. Celgene Filed Sham Litigations to Prevent or Delay Generic Entry.

343. In 2008, Celgene filed a patent infringement lawsuit against Barr, and in 2015 against Lannett, for their thalidomide ANDAs.

344. In 2010, Celgene filed a patent lawsuit against Natco for its lenalidomide ANDA. In 2016, Celgene filed a patent lawsuit against Dr. Reddy's for its lenalidomide ANDA. In 2017, Celgene filed patent lawsuits against Zydus Pharmaceuticals ("Zydus") and against Cipla Ltd. ("Cipla") for their lenalidomide ANDAs. In 2018, Celgene filed patent lawsuits against Lotus Pharmaceuticals ("Lotus"), Sun Pharmaceutical ("Sun"), Hetero Labs Ltd. ("Hetero"), and Apotex Inc. ("Apotex") for their lenalidomide ANDAs.

345. In all cases, Celgene complained that the generic versions of Thalomid and Revlimid infringed Celgene's patents related to its REMS procedures of ensuring safe use of the drug. Barr, Natco, Lannett, and Dr. Reddy's each counterclaimed, alleging that Celgene's patents are invalid as prior art or for obviousness, under 35 U.S.C. §§ 102 and/or 103. Because Celgene knew that its patents were invalid, it also must have known that the litigation to enforce the invalid patents would be unsuccessful. It brought the actions only because the filing would delay generic entry into the markets.

1. Celgene's Sham Litigation and Citizen Petition Against Barr.

346. Barr filed an ANDA with the FDA for a generic version of Thalomid in September 2006. In its application, Barr alleged that Celgene's patents were invalid.

347. As a result, Celgene filed a lawsuit against Barr in 2007, and a citizen petition on September 20, 2007, one year after Barr filed its ANDA with the FDA. The lawsuit was filed solely to take advantage of the 30-month statutory stay of FDA approval for Barr's generic thalidomide product. The patents at issue concerned the method-of-use rather than the pharmaceutical process; the patents were the result of academic conferences, and thus prone to invalidity on the grounds of obviousness. The litigation was a means to collusively and illegally ensure Celgene's continued monopoly.

348. In the lawsuit, Barr counterclaimed, alleging monopolization, conspiracy to monopolize, and anticompetitive acts, including sham litigation.

349. Upon information and belief, while that action was pending, Barr predicted that its generic version of Thalomid, thalidomide capsules in 50mg, 100mg, 150mg, and 200mg, would launch on the market on June 8, 2009. At the same time, it predicted filing an ANDA for its generic version of Revlimid, lenalidomide capsules, on December 27, 2009, and launching that product August 27, 2012.

350. In addition to filing sham litigation against Barr, on September 20, 2007, Celgene also filed a baseless citizen petition with the FDA urging it not to approve Barr's thalidomide ANDA. At a meeting with Celgene in 2012, FDA's Jane Axelrad, Associate Director for Policy at CDER, commented "since 2007, Celgene's citizen's petition states there are safety concerns and this is because the company does not want generics on the market." In its citizen petition, Celgene requested that the FDA withhold approval of any generic thalidomide product, or alternatively: i) require the application for generic thalidomide to be subject to the same conditions of approval applied to Thalomid under Subpart H of 21 C.F.R. Part 314; and ii) prohibit the restricted distribution program for the generic thalidomide product from authorizing prescriptions for, and registering patients with, multiple myeloma, in violation of Celgene's orphan drug exclusivity, which would expire in 2013.

351. Celgene's petition was meritless. It lacked any reasonable regulatory, scientific, medical, or other basis. The FDA lacked statutory authority to withhold approval of generic thalidomide on the bases given by Celgene or to require the actions Celgene requested. Like its litigation against Barr, this citizens petition was also a sham designed to maintain Celgene's monopoly.

352. On December 19, 2008, Barr responded to the petition, arguing that it "is nothing more than yet another attempt by a brand company to block all generic competition using market exclusivity protecting just a single approved indication." Barr explained that Celgene's pretextual safety concerns were "hyperbole designed to improperly play on the public's fears regarding thalidomide," and that Barr's proposed thalidomide would be safe and its label would contain all precautionary information contained in the Thalomid label. Specifically, Barr argued that the law permits it to carve-out from its label Thalomid's protected MM indication, and that "Barr's Thalidomide Labeling Need Not Contain The Multiple Myeloma Indication To Ensure The Safe And Effective Use Of The ANDA Product."

353. Nearly six years later, on September 30, 2014, the FDA denied Celgene's citizen petition, stating it "den[ies] your request that FDA decline to approve any ANDA for thalidomide."

354. Celgene's filing of baseless citizen petitions was part of, and advanced, its scheme to unlawfully monopolize the markets for the subject drugs.

355. Celgene's patent lawsuit against Barr initiated a 30-month stay of FDA approval for Barr's thalidomide ANDA pursuant to 21 U.S.C. § 355 (j)(5)(B)(iii).

356. The parties engaged in discovery through spring 2010. On May 5, 2010, as part of a settlement agreement, the terms of which are confidential, Barr/Teva[87] requested the FDA withdraw Barr's thalidomide ANDA. Barr/Teva withdrew its ANDA due to "lack of commercial viability" while maintaining that "we still believe Teva or another generic drugmaker may file a paragraph IV filing for Revlimid at some point despite the potential difficulties challenging a controlled-distribution program."[88] On May 26, 2010, the Court approved Barr and Celgene's

[87] Teva Purchased Barr in 2008.
[88] Exhibit to MSJ Opp. at PageIDs 17474, *Mylan*, No. 14-cv-2094 (D.N.J) ECF No. 285-17.

stipulation of dismissal. This settlement had the anticompetitive effect of keeping Barr's generic thalidomide and generic lenalidomide off the market.

357. The settlement's terms likely also included a reverse payment agreement from Celgene to Barr. A reverse payment patent settlement exists when a patent holder, here Celgene, settles a patent infringement action that the patent holder brought by making a payment to a potential competitor in consideration for their agreement to either delay or refrain from entering the patent holder's market.

358. This type of illegal and anticompetitive settlement artificially blocks competition, allowing Celgene to continue charging supra-competitive prices. When a patent holder can control an entire market through sham litigation, they can set supra-competitive prices for necessary products, leaving consumers with no choice but to pay the artificially inflated prices.

359. A reverse payment not only allows a patent holder to stranglehold a market, but it also indicates the invalidity of the brand manufacturer's -- Celgene's -- patents. Celgene's patents at issue concern method-of-use for Thalomid and Revlimid, rather than the pharmaceutical process itself. Moreover, Celgene's patents were largely based on academic and government studies and conferences and are thus prone to invalidity on the grounds of obviousness.[89] Celgene's patent litigation was not in good faith.

360. But for the confidential settlement which, upon information and belief, may have contained illegal pay-for-delay provisions, Barr would have pursued its 2008 thalidomide ANDA, filed a generic lenalidomide ANDA, and launched both of those products in 2009 and 2012, respectively. Celgene's conduct therefore had the anticompetitive effect of delaying and

[89] This is further supported by Congress's investigative findings that Celgene "relied heavily on taxpayer-funded academic research" in the use and development of its drugs. (**Ex. A**, p. 24 – September 2020 Report).

indefinitely postponing the testing and introduction of generic alternatives. This has caused great expense to Assignors, as a generic lenalidomide product has still never been brought to market.

2. Celgene's Sham Litigation Against Lannett.

361. After Celgene and Lannett reached a confidential settlement in 2011, in late 2013 Lannett announced that its bioequivalency studies were going well, and it expected to submit a thalidomide ANDA application to the FDA in January 2014. In December 2014, Lannett filed ANDA No. 206601 with the FDA to gain approval to market its generic version of Thalomid. Lannett also filed a Paragraph IV Certification, alleging that Celgene's patents were invalid.

362. Celgene filed a patent lawsuit against Lannett in response on January 30, 2015 alleging infringement of 15 different patents.[90] Lannett filed counterclaims against Celgene, alleging that each and every patent at issue was invalid, was unenforceable, or was not infringed by Lannett's Paragraph IV Certification.

363. Celgene's lawsuit triggered a 30-month statutory stay of FDA approval of Lannett's generic thalidomide product.[91]

364. On October 10, 2017, Celgene and Lannett stipulated to a settlement wherein Lannett would change its Paragraph IV Certification on the '745 Patent to a Paragraph III Certification and no longer seek FDA approval of its ANDA prior to the expiration of the '745 Patent, and Celgene would dismiss its claims of patent infringement.

365. On October 30, 2017, Lannett and Celgene announced that they entered into a settlement and license agreement related to Thalomid that would permit Lannett to manufacture and market its generic thalidomide product as of August 1, 2019. The terms of the license agreement are confidential.

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[90] *Celgene Corp. v. Lannett Holdings, Inc.*, No. 2:15-cv-00697 (D.N.J. Jan. 30, 2015) (Wigenton, J.).

[91] *See* 21 U.S.C. § 355(j)(5)(B)(iii).

366. The anticompetitive effect of Celgene's conduct was to delay Lannett's initial ANDA filing, and then to further delay FDA approval of Lannett's generic thalidomide product, and finally, to delay the entry date of Lannett's thalidomide product. There are currently no generic thalidomide products available for purchase.

3. Celgene's Sham Litigation Against Natco, Arrow, and Watson.

367. Natco Pharma is an Indian generic prescription drug manufacturer that partnered with Arrow and Watson to produce and market a generic version of Revlimid.

368. On or about August 30, 2010, Natco sent Celgene a required notice letter of its Paragraph IV Certifications, which contained a detailed factual and legal statement as to why Celgene's Distribution Method Patents, and certain patents that Celgene listed in the Orange Book in connection with NDA No. 21-880 that related to the chemical composition of Revlimid, including, the '517 Patent, 6,281,230 Patent ("'230 Patent"), 6,555,554 Patent ("'554 Patent"), 7,119,106 Patent ("'106 Patent"), and the '800 Patent, among others, are invalid, unenforceable, and /or not infringed by Natco's lenalidomide ANDA.

369. On approximately September 24, 2010, Natco filed ANDA No. 201452 seeking approval for 5 mg, 10 mg, 15mg and 20mg lenalidomide capsules. The ANDA showed that Natco's generic lenalidomide products are bioequivalent to Celgene's Revlimid.

370. Celgene filed a patent infringement suit against Natco on October 8, 2010. In November and December 2012, Celgene caused additional patents related to the chemical composition of Revlimid, patent number 8,288,415 ("'415 Patent") and the '886 Patent, respectively, to be listed in the Orange Book in connection with Revlimid.

371. On November 18, 2010, Natco filed its Answer and counterclaimed that its ANDA does not infringe Celgene's relevant patents, and that Celgene's relevant patents are invalid and unenforceable.

372. On March 14, 2013, Natco sent Celgene another required notice letter of its Paragraph IV Certifications, which contained a detailed factual and legal statement explaining that the '415 and '886 patents are invalid, unenforceable, and/or not infringed by Natco's lenalidomide generics.

373. On April 10, 2013, Celgene caused the '717 Patent to be listed in the Orange Book in connection with Revlimid. On April 30, 2013, the USPTO issued the'598 Patent to Celgene.

374. On May 6, 2013, Celgene filed its Fifth Amended Complaint against Natco Pharma, Arrow and Watson, claiming that Natco's lenalidomide generics would infringe the Distribution Method Patents, the '886 Patent, and the '517, '230, '554, '106, '800, '415, '717, and '598 patents. The invalidity of these patents is discussed above.

375. Natco argued that the '517, '230, '554, '106, '800, '415, '717, and '598 patents are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112 and/or doctrines of double patenting. Moreover, Natco argued that its lenalidomide generics do not infringe Celgene's '800 Patent as Natco's lenalidomide does not contain lenalidomide hemihydrate.

376. Celgene argued, and the Court agreed, that "hemihydrate" means "a hydrate containing approximately half a mole of water to one mole of the compound forming the hydrate."

377. Accordingly, using this definition, Celgene's '800 Patent is invalid under 35 U.S.C. § 112 for indefiniteness, and lack of written description and lack of enablement.

378. Natco filed counterclaims against Celgene, alleging fraud on the USPTO, and invalid and/or unenforceable patents. Celgene's sole purpose in litigating the alleged infringement was to delay generic entry into the Revlimid market.

379. On December 22, 2015, Celgene announced that it reached a settlement with Natco. On January 4, 2016, the District Court issued a consent judgment dismissing all claims with prejudice. Under the terms of the settlement agreement, Natco Pharma, Arrow, and Watson are

enjoined from marketing unlimited quantities of generic lenalidomide until January 1, 2026, one year before the expiration of the at issue patents. Starting in March 2022, Natco will be allowed to market a limited amount of generic lenalidomide. The allowed quantity will increase each year until 2026. "The volume limit is expected to be a mid-single-digit percentage of the total lenalidomide capsules dispensed in the United States during the first full year of entry. The volume limitation is expected to increase gradually each 12 months until March of 2025 and is not expected to exceed one-third of the total lenalidomide capsules dispensed in the U.S. in the final year of the volume-limited license."

380. The anticompetitive effects of Celgene's conduct were to delay Natco's ANDA and generic entry in the Revlimid market. Though Natco filed its lenalidomide ANDA in September 2010, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Assignors are forced to purchase brand-name Revlimid at Celgene's supra-competitive prices until at least 2022, and given volume limitations, likely until 2026.[92] This agreement functions as a "no authorized generic" provision because it restricts Celgene's ability to launch its own generic—thereby establishing a *quid pro quo* relationship where the generic brand (i.e. Natco) decreases competition in the generic brand market (by eliminating Celgene's ability to launch its own generic brand) in exchange for the generic brand (i.e. Natco) agreeing to stay off the market for a certain amount of years, thereby enabling Celgene to maintain its monopoly and continue to charge supra-competitive prices for its drugs for however many years agreed upon.

[92] *See* Luke M. Olson, Brett W. Wendling, *The Effect of Generic Drug Competition on Generic Drug Prices During the Hatch-Waxman 180-Day Exclusivity Period*, (Bureau of Econ., Fed. Trade Comm'n, Working Paper No. 317, Apr. 2017). https://www.ftc.gov/sites/default/files/documents/reports/estimating-effect-entry-generic-drug-prices-using-hatch-waxman-exclusivity/wp317.pdf (calculating that the addition of more than one generic competitor significantly lowers drug prices).

381. Additionally, the volume caps implemented by Celgene, and described above, protect the vast majority of Celgene's Revlimid prescription base from generic competition. The net result of the volume restriction and agreement to not launch an authorized generic is that Celgene retains its monopoly for brand Revlimid.

4. Celgene's Sham Litigation Against Dr. Reddy's.

382. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Dr. Reddy's. It brought the actions only because the filing would delay generic entry into the lenalidomide market.

a. Polymorphic Forms and Methods of Treatment Patents.

383. On October 20, 2016, Celgene filed yet another patent infringement action, this time against Dr. Reddy's, for filing its ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's '800 Patent,'217 Patent,'569 Patent, '498 Patent, '095 Patent, '621 Patent, and the '622 Patent.[93]

384. In its answer, filed on November 18, 2016, Dr. Reddy's claimed that all seven patents asserted were not duly and/or lawfully issued. It also counterclaimed that all seven patents were invalid and/or unenforceable. The parties filed opening Markman briefs on December 19, 2017. On March 23, 2018, Celgene notified the court that the parties resolved their claim construction disputes and would not be filing responsive Markman briefs.

385. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 13, 2020.

386. On September 17, 2020, the Court entered a consent judgment whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America,

[93] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J. Oct. 20, 2016).

including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[94]

387. The confidential settlement agreement, resolving all three patent litigations between Dr. Reddy's and Celgene, amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene had agreed to provide Dr. Reddy's "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning sometime after the March 2022 volume-limited license date that Celgene previously provided to Natco."[95] Dr. Reddy's would then obtain a license to market unlimited quantities of generic lenalidomide "no earlier than January 31, 2026,"[96] one year before the expiration of the at issue patents. Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[97] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Dr. Reddy's little to no incentive to lower its price because it cannot gain additional market share.[98] The new result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that

[94] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:16-cv-07704 (D.N.J. Sept. 16, 2020) ECF No. 175.
[95] *Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for REVLIMID (lenalidomide) With Dr. Reddy's*, BUSINESS WIRE (Sept. 17, 2020, 6:59AM) https://www.businesswire.com/news/home/20200917005211/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-With-Dr.-Reddy%E2%80%99s.
[96] *Id*.
[97] Letter at 7, n.11, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997, (D.N.J. May 21, 2019) ECF No. 288.
[98] Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018. 5:00AM) https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

Celgene retains its monopoly for the brand Revlimid. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market. The anticompetitive effects of Celgene's conduct were to delay Dr. Reddy's ANDA and generic entry into the Revlimid market. Though Dr. Reddy's filed its lenalidomide ANDA in 2016, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Assignors are forced to purchase brand-name Revlimid at Celgene's supra-competitive prices likely until 2026, given the volume limitations.

b. Additional Methods of Treatment Patents.

388. On July 20, 2017, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '740 Patent, '717 Patent, and '120 Patent.[99]

389. Dr. Reddy's filed its answer on October 3, 2017, and an amended answer on October 18, 2017. Celgene filed its Answer to Dr. Reddy's counterclaim on November 15, 2017.

390. A settlement conference was held on January 10, 2019. Expert discovery was set to close on March 26, 2020.

391. On March 2, 2020, the court ordered the parties to engage in confidential mediation, which was held on April 2, 2020.

392. On September 17, 2020, the Court entered a consent judgment whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '717 Patent, and '120 Patent.[100] As described above, this consent judgment

[99] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:17-cv-05314 (D.N.J.).
[100] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:17-cv-05314 (D.N.J. Sept. 17, 2020) ECF No. 120.

was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

393. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

c. Methods of Delivery Patents.

394. On April 12, 2018, Celgene filed suit against Dr. Reddy's for filing ANDA No. 209348 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent.[101]

395. Dr. Reddy's filed its answer and counterclaims on April 30, 2018, and an amended answer with counterclaims on May 31, 2018. Celgene filed its answer to Dr. Reddy's counterclaims on June 28, 2018.

396. On February 14, 2019, the parties agreed to stay the action until July 1, 2019. On July 1, 2019, the parties again agreed to stay the action through January 9, 2020, subject to renewal by the parties. On March 4, 2020, the parties again agreed to stay the action until June 15, 2020.

397. On September 17, 2020, the Court entered a consent judgment whereby Dr. Reddy's agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Dr. Reddy's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '720 Patent, '977 Patent, '784 Patent, '886 Patent, and '531 Patent.[102] As described above, this consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

[101] *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:18-cv-06378 (D.N.J.).
[102] Consent Judgment, *Celgene Corp. v. Dr. Reddy's Laboratories, Inc.*, No. 2:18-cv-06378 (D.N.J. Sept. 17, 2020) ECF No. 67.

398. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

5. Celgene's Sham Litigation Against Zydus

399. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Zydus. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

a. Polymorphic Form and Methods of Treatment Patents.

400. On April 12, 2017, Celgene filed a patent infringement action against Zydus and its healthcare arm, Cadila Healthcare Limited, for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly infringing Celgene's same '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent. This combination of patents has become central to Celgene's strategy of blocking generic competitors.

401. On August 7, 2017, Zydus filed its answer and counterclaimed that each of Celgene's asserted patents are invalid, unenforceable, or noninfringed.

402. On January 14, 2019, the Court ordered mediation between the parties.

403. On May 10, 2019, the Court issued an Amended Scheduling Order. On December 30, 2019, the court ordered the parties to present a final schedule for the remainder of expert discovery that took into account the age of the case.

404. On March 13, 2020, Celgene filed a motion, under seal, to stay the proceedings.

405. On March 24, 2021, the Court entered a consent judgment whereby Zydus agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Zydus's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent,'569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621 Patent, and

'622 Patent.[103] This consent judgment was pursuant to a settlement agreement that, upon information and belief, likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

406. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

b. Additional Polymorphic Form Patents.

407. On April 27, 2018, Celgene filed yet another patent infringement action against Zydus for filing ANDA No. 210154 for various dosages of its generic alternative to Revlimid, allegedly also infringing Celgene's '357 Patent, '219 Patent, and '598 Patent.[104]

408. On July 9, 2018, Zydus filed its answer.

409. On January 14, 2019, the court ordered mediation between the parties. Fact discovery closed on August 30, 2019.

410. On March 13, 2020, Celgene filed a motion, under seal, to stay the proceedings.

411. On March 24, 2021, the Court entered a consent judgment whereby Zydus agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Zydus's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent,'569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621 Patent, and '622 Patent.[105] This consent judgment was pursuant to a settlement agreement that, upon information and belief, likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

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[103] Consent Judgment, *Celgene Corp. v. Zydus Pharm*, No. 2:17-cv-2528 (D.N.J. Mar. 24, 2021) ECF No. 210.
[104] *Celgene Corp. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 2:18-cv-08519 (D.N.J.).
[105] Consent Judgment, *Celgene Corp. v. Zydus Pharm*, No. 2:18-cv-8519 (D.N.J. Mar. 24, 2021), ECF No. 119.

412. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

6. Celgene's Sham Litigation Against Cipla.

413. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Cipla. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

a. Polymorphic Form and Methods of Treatment Patents.

414. On August 15, 2017, Celgene filed a patent infringement action, this time against Cipla, for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the same combination of the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, and '622 Patent.[106]

415. On August 16, 2018, Celgene stipulated to a dismissal of its claims regarding the '217 Patent and filed a covenant not to sue Cipla for infringement of the '217 Patent.

416. On January 14, 2019, the Court ordered mediation between the parties. On February 6, 2019, the parties informed the court that Markman hearings were no longer necessary.

417. On June 4, 2019, the court entered an amended scheduling order. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731, discussed below.

418. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

b. Additional Polymorphic Form Patents.

419. On May 8, 2018, Celgene filed a patent infringement action against Cipla for filing its ANDA No. 210435 for various dosages of its generic alternative to Revlimid, which Celgene

[106] *Celgene Corp. v. Cipla Ltd.*, No. 2:17-cv-06163 (D.N.J.).

alleged would also infringe the same combination of the '357 Patent, '219 Patent, and '598 Patent.[107]

420. On July 16, 2018, Cipla filed its answer and counterclaims. On August 20, 2018, Celgene filed its answer to Cipla's counterclaim.

421. On April 30, 2019, the court issued a stipulated order in which the parties agreed not to contest a finding that products derived from Cipla's ANDA would infringe Celgene's patents at issue. On June 8, 2020, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 19-14731, discussed below.

422. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

c. Additional Litigation.

423. On July 3, 2019, Celgene filed another patent infringement action against Cipla for filing its ANDA No. 213165 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe the '800 Patent, '217 Patent, '569 Patent, '498 Patent, '095 Patent, '621 Patent, '622 Patent, '740 Patent, '717 Patent, and '120 Patent.[108]

424. On August 26, 2019, Cipla filed its answer and counterclaims, alleging that the patents at issue were all invalid, unenforceable, or would not be infringed by activity described in Cipla's Paragraph IV Certification for ANDA No. 213165. On October 18, 2019, Celgene filed its answer to Cipla's counterclaim.

[107] *Celgene Corp. v. Cipla Ltd.*, No. 2:18-cv-08964 (D.N.J.).
[108] *Celgene Corp. v. Cipla Ltd.*, No. 2:19-cv-14731 (D.N.J.).

425. On May 28, 2020, Celgene filed its First Amended Complaint, alleging that Cipla's ANDA would infringe every patent at issue in the prior two suits filed against Cipla.[109] On July 23, 2020, Celgene filed its answer to Cipla's counterclaims.

426. On December 14, 2020, Celgene and Cipla stipulated and consented to the entry of judgment and an injunction prohibiting Cipla from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.

427. The confidential settlement agreement, resolving all patent litigations between Cipla and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco, Dr. Reddy's, and, as below, Alvogen. In exchange for settling the litigations, Celgene has agreed to provide Cipla "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date that is some time after March 2022."[110] Cipla would then obtain a license to market volume-limited quantities of generic lenalidomide until January 31, 2026, one year before the expiration of the at issue patents.[111] While the exact percentages are confidential, Celgene has reserved for itself the vast majority of the market. Given the public terms available, which mostly mirror those struck with other would-be generic Revlimid and Thalomid manufacturers, Celgene is also likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[112] The volume caps described protect the

[109] First Amended Complaint, *Celgene Corp. v. Cipla Ltd.*, No 2:19-cv-14731, (D.N.J. May, 28, 2020) ECF No. 64.
[110] *Bristol Myers Squibb Announces Settlement of U.S. Patent Litigation for REVLIMID (lenalidomide) with Cipla*, BUSINESS WIRE (Dec. 11, 2020, 6:59AM) https://www.businesswire.com/news/home/20201211005052/en/Bristol-Myers-Squibb-Announces-Settlement-of-U.S.-Patent-Litigation-for-REVLIMID%C2%AE-lenalidomide-with-Cipla.
[111] *Id.*
[112] Letter at 7, n.11, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997 (D.N.J. May 21, 2019) ECF No. 288.

vast majority of Celgene's Revlimid prescription base from generic competition and give Cipla little to no incentive to lower its prices because it cannot gain additional market share.[113] As such, financial analysts concluded that the settlement was a "positive surprise," advising that "price erosion will remain much lower than in a multiplayer generic market," with the anticipated "staggered" entry of volume-limited generics likely to significantly defray natural price erosion until the volume limits expire in 2026."[114] Credit Suisse analysts estimate the settlement agreement delivers Cipla $300 million at net present value.[115] The net result of the pay-for-delay agreement and the likely agreement not to launch an authorized generic is that Celgene retains its monopoly for brand Revlimid. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that likely illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

7. Celgene's Sham Litigation Against Alvogen and Lotus.

428. As part of its unlawful anticompetitive strategy, Celgene filed two patent infringement suits against Lotus and Alvogen, Inc. ("Alvogen"). It brought the actions only because the filings would delay generic entry into the lenalidomide market.

a. Polymorphic Form, Distribution Method, and Methods of Treatment Patents.

429. On September 6, 2017, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '517 Patent, '720 Patent, '977 Patent, '784

[113] Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018. 5:00AM) https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.
[114] *Id*.
[115] *Id*.

Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent.[116]

430. On October 5, 2017, Lotus and Alvogen filed its answer and counterclaims, seeking declaratory judgments that the patents at issue were invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's paragraph IV Certification.

431. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing its generic lenalidomide until the expiration of the patents-in-suit listed above pursuant to a settlement agreement.

432. The confidential settlement agreement, resolving both patent litigations between Alvogen and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene has agreed to provide Alvogen "with a license to Celgene's patents required to manufacture and sell certain volume-limited amounts of generic lenalidomide in the United States beginning on a confidential date that is some time after the March 2022 volume-limited license date that Celgene previously provided to Natco."[117] Alvogen would then obtain a license to market volume-limited quantities of generic lenalidomide until January 31, 2026, one year before the expiration of the at issue patents.[118] While the exact percentages are confidential, Celgene has reserved for itself the vast majority of the market, with Alvogen's allotted volume increasing to only peak at "no more than a single-digit percentage in the final volume-limited period."[119] Celgene is also likely

[116] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al.*, No. 2:17-cv-06842 (D.N.J.).
[117] *Celgene Settles U.S. Revlimid Patent Litigation with Alvogen*, BUSINESS WIRE (MAR. 29, 2019) https://www.businesswire.com/news/home/20190329005384/en/Celgene-Settles-U.S.-REVLIMID%C2%AE-Patent-Litigation-with-Alvogen.
[118] *Id.*
[119] *Id.*

restricted from launching its own generic through penalties in the event an authorized generic product is launched.[120] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Alvogen little to no incentive to lower its prices because it cannot gain additional market share.[121] The net result of the pay-for-delay agreement and the agreement not to launch an authorized generic is that Celgene retains its monopoly for the brand Revlimid.

433. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that includes illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

b. Additional Polymorphic Form Patents.

434. On July 10, 2018, Celgene filed a patent infringement action against Lotus and Alvogen for filing ANDA No. 210480 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent, '219 Patent, and the '598 Patent.[122] The patents that Celgene has claimed would be infringed in this case, however, have not been submitted to the Orange Book by Celgene in association with Revlimid as required pursuant to 21 U.S.C. §355(b)(1) and attendant FDA regulations. Celgene was required to list with its NDA, or within thirty days for a new patent after the NDA has been submitted, any patents for which an infringement claim could reasonably be asserted against an unlicensed entity attempting to manufacture, use or sell its drug. By citing these patents that were not filed in the Orange Book,

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[120] Letter at 7, n.11, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997 (D.N.J. May 21, 2019) ECF No. 288.

[121] Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018. 5:00AM) https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

[122] *Celgene Corp. v. Lotus Pharmaceutical Co., Ltd., et al*, No. 2:18-cv-11518 (D.N.J.).

Celgene is either filing a frivolous infringement claim for a patent that it does not believe could be reasonably asserted or failing to list patents properly which could give rise to administrative action or potentially additional antitrust liability if done in an attempt to delay filing and further extend its monopoly.

435. In their notice letter to Celgene, Lotus and Alvogen also alleged that the '517 Patent, '720 Patent, '977 Patent, '784 Patent, '740 Patent, '800 Patent, '217 Patent, '569 Patent, '886 Patent, '717 Patent, '498 Patent, '531 Patent, '095 Patent, '120 Patent, '621 Patent, and the '622 Patent were all invalid, unenforceable, or would not be infringed by activity described in Lotus and Alvogen's Paragraph IV Certification.

436. On March 29, 2019, Celgene, Lotus, and Alvogen stipulated and consented to an entry of judgment and an injunction prohibiting Lotus and Alvogen from marketing and selling its generic lenalidomide until the expiration of the patents-in-suit listed above. As described above, this consent judgment was pursuant to a settlement agreement that also likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

437. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation and inducing another confidential settlement agreement with a generic competitor that include illegal pay-for-delay provisions, are to delay and prevent generic entry into the lenalidomide market.

8. Celgene's Sham Litigation Against Sun.

438. In Spring 2018, Sun filed its ANDA No. 211846 for generic lenalidomide. On May 30, 2018, Sun sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Sun's ANDA.

439. On July 13, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Sun Pharmaceuticals Industries, Inc. and related entities

for filing its ANDA for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, and their '569 Patent.[123]

440. On August 14, 2018, Sun filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed.

441. On November 21, 2019, the court issued an amended scheduling order. On December 12, 2019, the court canceled Markman hearings upon the parties' joint motion.

442. On June 22, 2021, the Court entered a consent judgment whereby Sun agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Sun's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '800 Patent, '217 Patent, '569 Patent, '357 Patent, '219 Patent, '598 Patent,'498 Patent, '095 Patent, '621 Patent, and '622 Patent.[124]

443. The confidential settlement agreement, resolving all three patent litigations between Sun and Celgene, likely amounts to another unlawful "pay-for-delay" agreement similar to Celgene's settlement agreement with Natco. In exchange for settling the litigations, Celgene had agreed provide Sun "with a license to Celgene's patents required to manufacture and sell certain limited quantity of generic lenalidomide capsules in the US beginning on a confidential date that is sometime after March 2022."[125] Sun would then obtain a license to market unlimited quantities of generic lenalidomide capsules beginning January 31, 2016,[126] one year before the

[123] *Celgene Corp. v. Sun Pharm. Indus., Inc., et al.*, No. 2:18-cv-11630 (D.N.J.).
[124] Consent Judgment, *Celgene Corp. v. Sun Pharm. Indus., Inc.*, *et al.,* No. 2:18-cv-11630 (D.N.J. Jun. 22,2021), ECF No. 119.
[125] *Sun Pharma Announces Settlement of Patent Litigation for Generic Revlimid (lenalidomide) in U.S.*, SUN PHARMA (Jun. 22, 2021) https://sunpharma.com/wp-content/uploads/2021/06/Press-Release-Settlement-of-Patent-Litigation-for-Generic-Revlimid-in-US.pdf.
[126] *Id*.

expiration of the at issue patents. Celgene is likely restricted from launching its own generic through penalties in the event an authorized generic product is launched.[127] The volume caps described protect the vast majority of Celgene's Revlimid prescription base from generic competition and give Sun little to no incentive to lower its price because it cannot gain additional market share.[128] The new result of the pay-for-delay agreement and the agreement not to launch an authorized generic is that Celgene retains its monopoly for the brand Revlimid. The anticompetitive effects of Celgene's conduct are to again delay and prevent generic entry into the lenalidomide market.

444. The anticompetitive effects of Celgene's conduct were to delay Sun's ANDA and generic entry into the Revlimid market. Though Sun filed its lenalidomide ANDA in 2018, it cannot bring its generic to market until 2022 at limited volumes. Consequently, a generic lenalidomide product continues to be unavailable and Assignors are forced to purchase brand-name Revlimid at Celgene's supra-competitive prices until at least 2022, and given volume limitations, likely until 2026.

9. Celgene's Sham Litigation Against Hetero.

445. As part of its unlawful anticompetitive strategy, Celgene filed three patent infringement suits against Hetero. It brought the actions only because the filings would delay generic entry into the lenalidomide market.

a. Polymorphic Forms and Methods of Treatment Patents.

[127] Letter at 7, n.11, *In re Thalomid and Revlimid Antitrust Litigation*, No. 2:14-cv-06997 (D.N.J. May 21, 2019) ECF No. 288.
[128] Alison Kodjak, *How a Drugmaker Gamed the System to Keep Generic Competition Away*, NPR (May 17, 2018. 5:00AM) https://www.npr.org/sections/health-shots/2018/05/17/571986468/how-a-drugmaker-gamed-the-system-to-keep-generic-competition-away.

446. In the Fall 2018, Hetero filed its ANDA for generic lenalidomide. On November 9, 2018, Hetero sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-suit are invalid and/or will not be infringed by Hetero's ANDA.

447. On December 20, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Hetero Labs, Ltd,[129] for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[130]

448. On March 11, 2019, Hetero filed its answer and counterclaim, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. On April 15, 2019, Celgene filed its answer to Hetero's counterclaim.

449. On January 21, 2020, the court entered a stipulation dismissing without prejudice Celgene's claims relating to the '217 Patent, '363 Patent, and the '929 Patent. The case went forward only as to the '800 Patent.

450. On January 11, 2021, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 20-14389, discussed below.

451. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

b. Additional Methods of Treatment Patents.

452. On July 16, 2019, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid,

[129] The complaint also named Hetero Labs Limited Unit-V, Hetero Drugs Limited, and Hetero USA, Inc. (collectively, "Hetero").
[130] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:18-cv-17463 (D.N.J.).

which Celgene alleged would infringe its '740 Patent, '569 Patent, '717 Patent, '498 Patent, '095 Patent, '120 Patent, '621 Patent, and '622 Patent.[131]

453. On October 11, 2019, Hetero filed its answer and counterclaims against Celgene, for which Celgene filed an answer on November 15, 2019.

454. On December 18, 2019, the court issued a pretrial scheduling order.

455. On January 11, 2021, the docket was administratively terminated, with the filings of the docket remaining in force and incorporated by reference into Civil Action No. 20-14389.

456. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

c. Additional Litigation.

457. On October 13, 2020, Celgene filed yet another patent infringement action against Hetero for filing ANDA No. 212414 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '357 Patent and '219 Patent.[132]

458. On November 13, 2020, Hetero filed its answer and counterclaims against Celgene.

459. On January 8, 2021, Celgene filed an amended complaint. On January 26, 2021, Hetero filed its answer to same and counterclaims against Celgene. Celgene filed its answer to counterclaims on February 23, 2021.

460. On September 27, 2021, the Court entered a consent judgment whereby Hetero agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Hetero's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '800 Patent, '569 Patent, '357 Patent, '219 Patent,'717 Patent, '498 Patent, '095

[131] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:19-cv-15449 (D.N.J.).
[132] *Celgene Corp. v. Hetero Labs Ltd., et al.*, No. 2:20-cv-14389 (D.N.J.).

Patent, '120 Patent, '621 Patent, and '622 Patent.[133] This consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

461. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

10. Celgene's Sham Litigation Against Apotex.

462. In Winter 2017, Apotex filed its ANDA for generic lenalidomide. On November 28, 2017, Apotex sent written notice of its Paragraph IV Certification to Celgene alleging that the patents-in-issue are invalid and/or will not be infringed by Apotex's ANDA.

463. On January 11, 2018, Celgene filed yet another patent infringement action against a generic manufacturer, this time against Apotex for filing ANDA No. 211022 for various dosages of its generic alternative to Revlimid, which Celgene alleged would infringe its '720 Patent, '977 Patent, '784 Patent, '886 Patent, '531 Patent, '800 Patent, '217 Patent, '363 Patent, and '929 Patent.[134]

464. On August 30, 2018, Apotex filed its answer and affirmative defenses, alleging that Celgene's asserted patents are invalid, unenforceable, or uninfringed. Apotex alleged that five of the patents-in-suit are unenforceable due to patent misuse because Celgene asserted the patents even though no reasonable litigant could believe they were valid in light of prior proceedings in front of the PTAB.

465. On April 30, 2019, the court issued a consent judgment that the '217 Patent was not infringed by ANDA No. 211022.

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[133] Consent Judgment, *Celgene Corp. v. Hetero Labs,* No. 2:20-cv-14389 (D.N.J. Sept. 27, 2021) ECF. No. 51.
[134] *Celgene Corp. v. Apotex Inc.*, No. 2:18-cv-00461 (D.N.J.).

466. On May 8, 2019, the court issued an order bifurcating the claims and staying the action as to the '720 Patent, '977 Patent, '784 Patent, '886 Patent, and the '531 Patent.

467. The case proceeded as to claims concerning the '800 Patent, '363 Patent, and the '929 Patent.

468. On March 10, 2021, the Court entered a consent judgment whereby Apotex agreed to refrain from making, having made, using, selling, offering to sell, importing, or distributing Apotex's generic version of Revlimid in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico until the expiration of Celgene's '740 Patent, '800 Patent, '363 Patent, '357 Patent, '219 Patent,'717 Patent, '598 Patent, '929 Patent, and '120 Patent.[135] This consent judgment was pursuant to a settlement agreement that likely contained anticompetitive provisions amounting to a "pay-for-delay" agreement.

469. The anticompetitive effects of Celgene's conduct, including filing yet another sham litigation, are to delay and prevent generic entry into the lenalidomide market.

VII. CELGENE INTENDED TO AND DID HARM COMPETITION.

470. Celgene's scheme was intended to and did in fact block and delay generic thalidomide and lenalidomide entry into the market, disrupted the normal distribution channels, and manipulated the statutory and regulatory mechanisms by which generic competition takes place, and otherwise excluded generic competitors from efficiently marketing and distributing their products.

471. But for Celgene's anticompetitive scheme, generic Thalomid would have been brought to market at least as early as spring of 2009. Celgene illegally prevented competitors, including Mylan in 2004, Barr in 2005, and Lannett and 2007, from obtaining Thalomid samples

[135] Consent Judgment, *Celgene Corp. v. Apotex Inc.,* No. 2:18-cv-00461 (D.N.J. Apr. 30, 2019) ECF No. 63.

for bioequivalence testing. When Barr filed its ANDA in September 2005, Celgene executed a contract with Barr's API supplier that contained an anticompetitive exclusive dealing provision that created deficiencies in Barr's ANDA application and required Barr to undergo new bio-studies and validation testing, delaying Barr's ANDA one year. When Barr filed its ANDA in September 2006, Celgene filed a sham litigation suit to enforce its invalid and unenforceable patents. The litigation was halted when Celgene and Barr reached a confidential settlement which resulted in a continued absence of generic Thalomid from the market.

472. But for Celgene's anticompetitive conduct, generic Revlimid would have entered the market in 2010 or soon thereafter. Celgene once again prevented multiple competitors including Mylan, Natco Pharma, Dr. Reddy's, Teva, and Watson from obtaining Revlimid from Celgene for bioequivalency testing. Celgene refused to supply samples to Mylan, and Mylan has been unable to complete bioequivalency testing or file an ANDA for lenalidomide. Natco filed its lenalidomide ANDA in September 2010 and would have brought generic Revlimid to market shortly thereafter, but for Celgene's sham patent infringement lawsuit and the subsequent settlement wherein Natco agreed not to sell generic lenalidomide until 2022, and then only in limited quantities. Dr. Reddy's filed its lenalidomide ANDA in 2016, after which Celgene once again filed a sham patent litigation. Lannett filed its thalidomide ANDA in December 2014, after which Celgene filed a sham patent litigation that resulted in a settlement wherein Lannett's thalidomide cannot be sold until August 2019. Zydus, CIPLA, Lotus, Hetero, Apotex and Sun each filed lenalidomide ANDAs and were met with Celgene's serial sham litigation tactic, delaying the entry of their generic Revlimid products into the market.

473. All of Celgene's patents on Revlimid are invalid under 35 U.S.C. §§ 101, 102, 103, 112, and/or the doctrines of double-patenting.

474. Further, the Committee on Oversight and Reform of the U.S. House of Representatives issued a report in December 2021 based on an investigation into drug pricing.[136] One of several findings included in the report was the conclusion that Celgene (which is synonymous with BMS for purposes of this Amended Complaint) will continue to have a monopoly with Revlimid until "at least 2026." [137]

475. Celgene's unjustifiable refusal to cooperate with the generic ANDA filers directly prevented generic filers from obtaining FDA approval. But for Celgene's unlawful conduct, the FDA would have given final approval to the pending generic manufacturer's ANDAs and allowed them to enter the market.

476. Celgene cannot justify its scheme by pointing to any consumer benefit. Generic drugs offer enormous cost savings, which outweigh any non-pretextual, if there even are any, justifications Celgene could possibly offer.

VIII. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID CAUSED ASSIGNORS TO PAY MORE THAN THEY WOULD HAVE PAID IN AN UNMANIPULATED MARKET.

477. Celgene's scheme suppressed the ability of generic Thalomid and Revlimid substitutes to compete in the market under the governing statutory and regulatory scheme.

478. The absence of generic competition injured Assignors as they would have paid much less for Thalomid and Revlimid, or their generic alternatives, by substituting purchases of less expensive AB-rated generic drugs for their purchases of more expense branded drugs, receiving discounts on their remaining purchases of branded drugs, and by purchasing generic versions of Thalomid and Revlimid at lower prices sooner.

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[136] *Drug Pricing Investigation*, COMMITTEE ON OVERSIGHT AND REFORM, U.S. HOUSE OF REPRESENTATIVES, pp 94-95 (Dec. 10, 2021) (Attached hereto as **Exhibit B**).
[137] *Id.*

479. As a result, Assignors sustained and continue to sustain substantial losses and damages to their business and property in the form of overcharges, the exact amount of which will be the subject of proof at trial.

IX. CELGENE'S FORECLOSURE OF GENERIC COMPETITION FOR THALOMID AND REVLIMID AFFECTED INTERSTATE COMMERCE FOR THOSE DRUGS.

480. At all material times, Thalomid and Revlimid, manufactured and sold by Celgene, were shipped across state lines and sold to customers located outside of its state of manufacture.

481. Between at least 2010 and the present, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills and other forms of business communication and transactions were transmitted in a continuous and uninterrupted flow across state lines.

482. At all material times, various devices were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Celgene as charged were within the flow of, and have substantially affected interstate commerce, money, contracts, bills, and other forms of business communications and were transmitted in a continuous and uninterrupted flow across state lines.

X. CELGENE MAINTAINED MONOPOLY POWER OVER THALOMID AND REVLIMID AND THEIR GENERIC FORMS.

483. At all relevant times, Celgene has had power over the market for Thalomid and Revlimid in all their forms and dosages, which are still only available in the form of branded Thalomid and branded Revlimid. Celgene has and continues to have the power to maintain and increase the price of Thalomid and Revlimid to supra-competitive levels without losing sales, because Celgene has successfully conspired to keep AB-rated generic versions of Thalomid and Revlimid from reaching the U.S. market at all.

484. A small, but significant, non-transitory price increase for Revlimid or Thalomid by Celgene would not have caused a significant loss of sales.

485. Celgene needed to control only Thalomid and Revlimid and their AB-rated generic equivalents, and no other products, to maintain the price of Thalomid and Revlimid at supra-competitive prices. Only the market entry of a competing AB-rated generic version of those drugs would render Celgene unable to maintain its market monopoly.

486. If Plaintiffs are legally required to prove market power through circumstantial evidence by first defining a relevant product market, the relevant market for Thalomid is all dosages of thalidomide, *i.e.*, Thalomid and its AB-rated generic equivalents, and for Revlimid is all dosages of lenalidomide, *i.e.*, Revlimid and its AB-rated generic equivalents.

487. Thalomid and Revlimid do not exhibit significant, positive cross-elasticity of demand regarding price with any other product, due to the FDA regulatory hurdles incident to securing AB rating and laws allowing pharmacists to substitute only AB-rated generics for prescribed branded drugs.

XI. CELGENE MONOPOLIZED THE RELEVANT MARKET

488. There are no interchangeable drug products available for purchasers of Thalomid and Revlimid.

489. Celgene needed to control the output of Thalomid and Revlimid and its AB-rated generic equivalents only, and no other products, to maintain the price of Thalomid and Revlimid profitably at supra-competitive prices. Only the market entry of a competing AB-rated generic version of Revlimid or Thalomid would render Celgene unable to profitably maintain its current prices of those drugs without losing substantial sales.

490. Celgene also sold branded Thalomid and Revlimid well over marginal costs, and substantially more than the competitive price, and enjoyed unusually high profit margins.

491. Celgene has had, and so exercised, the power to exclude and restrict competition for Thalomid and Revlimid.

492. Without the power to exclude and restrict competition for Thalomid and Revlimid, and the ability to sell its own branded version of those drugs at prices well over marginal costs, it would not have been economically rational for Celgene to pay Natco, and the other generic manufacturers identified above, unusually exorbitant settlement payments to delay the launch of generic Thalomid and Revlimid.

493. At all relevant times, Celgene has enjoyed the benefits of high barriers to entry with respect to competition to the above-defined market due to patent and other regulatory protections.

494. The relevant geographic markets are (i) the United States and its territories, and (ii) each of the states in which an Assignors' Enrollees purchased and/or a Health Plan paid for or reimbursed the cost of Revlimid and/or Thalomid and under whose laws Plaintiffs assert claims for relief. At all relevant times, Celgene's market share in the relevant market was, and continues to be, 100%.

XII. ANTITRUST INJURY.

495. Celgene's use of the regulatory process as an anticompetitive tool to block and delay generic competition for Thalomid and Revlimid keeps costs high for insurers like Assignors.

496. Assignors paid substantial sums to purchase Thalomid and Revlimid during the relevant times and their members paid additional sums in cost-sharing for Thalomid and Revlimid. As a result of Celgene's illegal conduct, Assignors paid artificially inflated prices for Thalomid and Revlimid. Those prices have been substantially higher than the prices Assignors would have paid for generic Thalomid and generic Revlimid but for the illegal conduct alleged herein. Health Plans continue to pay artificially high, supra-competitive prices for Thalomid and Revlimid as a direct result of Celgene's anticompetitive conduct.

497. Consequently, Assignors, as purchasers of Thalomid and Revlimid, having paid for Thalomid and Revlimid, have sustained substantial losses and damage to their business and property in the form of overcharges. These losses and damages are continuing and accumulating. The full amount, forms, and components of such damages will be determined after discovery and upon proof at trial.

498. Celgene's efforts to restrain competition in the defined relevant markets has and continues to substantially affect interstate and intrastate commerce throughout the United States.

499. In total, Plaintiffs' data shows that Assignors paid **$251,449,930.22** towards Thalomid and Revlimid at supra-competitive levels and continue to do so.

500. Excluding generic competitors prevented price competition for Thalomid and Revlimid.

501. Prices for Thalomid and Revlimid have been and will continue to be inflated as a direct and foreseeable result of Celgene's anticompetitive and fraudulent conduct. The inflated prices that Assignors have paid and will continue to pay are traceable to, and the foreseeable result of, the overcharges by Celgene.

XIII. CELGENE EMPLOYS 501(c)(3)S AS A CONDUIT TO COMMIT ADDITIONAL RICO AND ANTITRUST INJURIES.

502. At the same time Celgene was engaged in the anticompetitive and fraudulent conduct described above, Celgene was also entering into the Co-Payment Circumvention Enterprise to wit, secret agreements with "independent" third-party charities, namely Defendants CDF and PANF, to act as conduits for underwriting co-payments for Thalomid and Revlimid . Celgene used this scheme, even though it violated multiple laws, to eliminate the Enrollees' price sensitivity, leaving third-party payors solely responsible for paying for those prescriptions. As a proximate result of those agreements, Celgene was able to, and did, increase both the price and quantity sold of Thalomid and Revlimid. The agreements between Celgene and CDF and Celgene

and PANF harmed competition in the markets for Revlimid and Thalomid and other oncology drugs.[138]

503. Co-payment circumvention schemes like the ones implemented by Defendants provide a "triple boom" because "[t]hey increase demand, allow companies to charge higher prices, and provide public-relations benefits."[139,140]

504. The only entities harmed in these types of schemes are third party payers such as Assignors and the Class Members. This is principally because there are no violations of law among the chain of distribution until the unlawful co-payment is provided through the conduit (from Celgene) and a bill is submitted to the third-party payer. Additionally, wholesale distributors, specialty distributors, and/or pharmacies actually benefit from the scheme as their sales increase *because the rate of abandonment decreases*, as well as revenue from service fees which are based

[138] When Medicare beneficiaries, including those covered by Medicare Advantage health plans, obtain a prescription drug, the beneficiaries are, more likely than not, required to make a co-payment. Congress included co-payment requirements in the Medicare structure, in part, to encourage market forces to serve as a check on health care costs, specifically including the prices that pharmaceutical companies can demand for their drugs. Austin, Frerick A., *The Cloak of Social Responsibility: Pharmaceutical Corporate Charity*, TAX NOTES, Vol. 153, No. 9, Nov. 28, 2016.
[139] David H. Howard, *Drug Companies' Patient-Assistance Programs -- Helping Patients or Profits*, 371 NEW ENG. J. MED. 97, (2014).
[140] Arguably it's more like a grand finale as the manufacturers also gain tax benefits from the "donations." *See* Howard above.

on a percentage of the Wholesale Acquisition Cost ("WAC").[141,142] These incentives ensure that the supply chain does not quibble over increased WAC prices.[143]

505. Such plans can prove problematic for health plans that bear the increased cost of the drugs as it costs more to insure enrollees.

506. Having worked to exclude generics from the market under the conduct described above and secure for itself a monopoly in the markets for Revlimid and Thalomid, Celgene consistently raised the price of Revlimid and Thalomid year-over-year, despite the fact that Celgene knew that many patients already had a difficult time paying their co-payment.

507. For example, since Revlimid's launch, Celgene has implemented more than twenty price increases, causing the price to skyrocket 255%. The cost of a year's worth of Revlimid currently costs upwards $192,000.[144]

508. At the end of 2007, a single dose of Revlimid cost $247.28, the same dose cost $719.82 in 2019.[145]

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[141] Prescription abandonment—when a prescription is transmitted to the pharmacy but never filled—is a major concern for both providers and drug manufacturers. Prescription abandonment is multi-faceted, but it is widely understood that high co-payments are a leading cause and lowering co-payments significantly reduces abandonment for highly effective chronic treatments. Dana P. Goldman et al., *Prescription Drug Cost Sharing: Associations with Medication and Medical Utilization and Spending and Health*. 298.1 Jama 61, 61-69 (2007). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6375697/

[142] Prescription abandonment causes an estimated 125,000 avoidable deaths in the U.S. annually. Regardless of whether patients and doctors are induced by PAP funds at the prescription stage, the data is clear that patients are induced by co-payment assistance at the dispensing stage. Hayden B. Bosworth et al., *Medication Adherence: A Call for Action*. 162.3 Am Heart J. 412 (2011). Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3947508/

[143] Additionally, these entities have discount agreements with the pharmaceutical manufacturer, offering the supply chain additional incentives to remain quiet over increased WAC prices. Publication of OIG Special Fraud Alerts, 59 FR 65372-01 (1997).

[144] *Drug Pricing Investigation*, Committee on Oversight and Reform, U.S. House of Representatives, p 14 (Dec. 10, 2021) (Attached hereto as **Exhibit B**).

[145] *Celgene Hikes Price of Popular Cancer Drug Revlimid*, WASHINGTON POST (Jan. 4, 2019) https://www.washingtonpost.com/business/economy/celgene-hikes-price-of-popular-cancer-drug-revlimid/2019/01/04/01d83628-102c-11e9-8938-5898adc28fa2_story.html.

509. Also in 2007, Celgene began reporting substantial "donations" to certain purportedly "independent" third-party charities that provided co-payment assistance.[146]

510. Celgene realized it could overcome doctor and patient cost concerns, and more importantly to them, drive up prescription volume by secretly subsidizing patient co-pay obligations for its drugs through such charities.

511. Since 2007, Celgene has made purported "donations" to CDF and PANF in amounts estimated to be between $50 and $100 million per year.[147]

512. In fact, Celgene bribed and colluded with CDF and PANF as conduits to provide the co-payments to enrollees, circumventing mandated cost sharing obligations. Celgene's payments operated as intended, allowing Celgene to artificially inflate the prices of Revlimid and Thalomid as ultimately paid by third party payors—including Assignors and the Class Members.[148]

513. CDF and PANF used the bribes they received from Celgene to pay patients' co-pays for Revlimid and Thalomid, just as Celgene intended, therefore preventing patients and doctors from objecting to Celgene's consistent price increases for the drugs.[149]

514. Celgene thus used the co-pay "charities" (that Celgene funded) to effectively relieve a remaining market constraint on the prices that it could charge for its drugs, *i.e.*, patient and doctor sensitivity to price.

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[146] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2007*, p 40 (Feb. 20, 2008) ("2007 Celgene 10-K"). **Ex. O** – Excerpts of Celgene 10-K Reports.

[147] (**Ex. A** – *Drug Pricing Investigation: Celgene and Bristol Myers Squibb—Revlimid*, Committee on Oversight and Reform, U.S. House of Representatives (September 2020) ("Congressional Revlimid Report"); *See also* Stultz Deposition Transcript, pp 255-266, *United States of America et al v. Celgene*, 2:10-cv-03165, (N.D. Cal.) ECF No. 305-3.

[148] Dr. Hay Report, pp 67-73, *United States of America et al v. Celgene*, 2:10-cv-03165 (N.D. Cal.) ECF No. 329-19 ("Dr. Hay Report").

[149] Dr. Hay Report, pp 70-71.

515. It is well recognized that an insured's co-pay sharing obligations serves as a market-based check on drug pricing. By surreptitiously underwriting these cost-sharing obligations, Celgene created the illusion for physicians and patients that Revlimid and Thalomid were "free" (or close to it) when Celgene had merely shifted the entire price burden to third-party payors, including Assignors and the Class Members. Celgene knew it could easily make up the "losses" it incurred in making the payments to the charities with the profits earned from increasing prices, thus gaining additional sales, and through tax deductions.

516. For these reasons, the federal government has long instructed that such conduct violates federal law as unlawful bribes, known as "kickbacks," when conducted in connection with patients insured under Medicare, Medicare Advantage, and Medicare Part D plans. For example, in 2005, the United States Department of Health and Human Services, Office of the Inspector General ("OIG") issued a "Special Advisory Bulletin on Patient Assistance Programs," warning that pharmaceutical manufacturers' subsidization or influence or affiliation in providing assistance for patients' cost-sharing obligations—whether "directly or indirectly" (including "through" a charity)—is illegal.[150] Among other things, it warned against the following:

- The improper "use of cost-sharing subsidies to shield beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices."

- So long as the manufacturer's sales price for the product exceeds it marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. **These profits can be considerable, especially for expensive drugs for chronic conditions.** We are concerned that pharmaceutical manufacturers may seek improperly to maximize these profits by creating sham "independent" charities to operate PAPs[[151]]; **by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products**…." (emphasis added).

[150] *Special Advisory Bulletin: Patient Assistance Programs for Medicare Part D Enrollees*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, 70 Fed. Reg. 70623-03 (Nov. 22, 2005).
[151] Patient Assistance Programs ("PAP").

517. In 2014, OIG issued a Supplemental Bulletin on pharmaceutical companies' "indirect remuneration to patients" through "contributions to PAP[s]" operated by independent charities.[152] In that Supplemental Bulletin, OIG reiterated that "[i]f a donation is made to a PAP to induce the PAP to . . . arrange for the purchase of the donor's federally reimbursable items, the [antikickback] statute could be violated."

518. In the 2014 Bulletin, OIG expressed specific concern regarding situations where non-profits "define[d] their disease funds so narrowly that earmarking effectively results in a donor's subsidization of its own products." OIG noted that "[a] charity with narrowly defined disease funds may be subject to scrutiny if the disease funds result in funding exclusively or primarily the products of donors or if other facts and circumstances suggest that the disease fund is operated to induce the purchase of donors' products." As a result, funds are "subject to more scrutiny if [they are] limited to a subset of available products, rather than all products approved by the FDA for treatment of the disease state(s) covered by the fund or all products covered by the relevant Federal health care program when prescribed for the treatment of the disease states (including generic or bioequivalent drugs)."

519. In the Supplemental Bulletin, OIG also emphasized that independent charities cannot "give a donor any information that would enable a donor to correlate the amount or frequency of its donations with the number of aid recipients who use its products or services or the volume of those products supported by the PAP."

520. In facilitation of its scheme here, Celgene maintained close contact and worked in coordination with the charities to effectuate its goals. Celgene's payments were not made on an *ad hoc* basis. Instead, they were based on contractual arrangements under which Celgene agreed to pay designated amounts of money to designated disease funds; and addendums were frequently

[152] *Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs*, DEPARTMENT OF HEALTH AND HUMAN SERVICES, 79 Fed. Reg. 31120-31123 (May 30, 2014).

entered to ensure all co-pays would be funded as co-pay projections (or actual payouts on Celgene drugs) changed. CDF routinely provided Celgene both with co-pay forecasts for the following year as well as co-pay utilization. Indeed, the contracts between Celgene and CDF require CDF to regularly produce status reports to Celgene with information on the number of applicants, average amounts of co-pays, total amounts paid out, and the amount of Celgene's donation that remains available for use. Contracts with PANF require PANF's provision of virtually identical information.[153] These bribes and communications were sent through the U.S. mail and wire and in furtherance of the illegal scheme to extract more money from Assignors.

521. CDF and PANF conspired with Celgene and third parties to provide Celgene with the information it needed to be able to ensure it would fully fund and offset potential co-pays as needed for the continued sale of its own products (notwithstanding the exorbitant prices born by payors), and that it successfully aligned its funding accordingly.[154]

522. With the information it obtained from these purportedly "independent" charities, Celgene and the charities were effectively able to conduct return on investment ("ROI") analyses on the amounts of Celgene's "donations," showing Celgene's profits from this scheme.[155]

523. In fact, CDF's own records contained the following statement: "In other words, $100 million in increased donations to copay assistance programs like those run by the CDF can ultimately generate $1 billion in incremental drug sales for CELG[ENE]."[156]

524. Communications exchanged between CDF with PANF employees reveal that both CDF and PANF understood the purpose and effect of Celgene's payments, stating for example:

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[153] Dr. Hay Report, pp 72-73.
[154] *Id*., pp 72-73.
[155] *Id*., pp 71-73.
[156] Ikarian Point Research, *Celgene and the Chronic Disease Fund: The Next Domino to Fall?*, SEEKINGALPHA, (Dec. 11, 2013) https://seekingalpha.com/article/1892111-celgene-and-the-chronic-disease-fund-the-next-domino-to-fall ("SeekingAlpha Article").

"If the CDF were to shut down or curtail its operations significantly it would be a big problem for CELG[ENE] because ***the CDF's copay assistance program drives a large proportion of CELG[ENE]'s revenues***." (emphasis added).[157]

525. Celgene routinely communicated with the charities to assure that its bribes—disguised as donations—were sufficient to keep funds flowing towards potential users of Celgene drugs and drive its profits while third party payors paid artificially high and increasing prices.[158]

526. Celgene thus employed an illegal scheme of providing charitable "donations" to "independent" non-profits, which were actually kickbacks and subsidies designed to interfere with market forces and maintain and further inflate the prices and increase the use of Revlimid and/or Thalomid as ultimately paid by healthcare payors such as Assignors and the Class Members

527. On October 25, 2019, CDF and PANF entered into settlements with the DOJ in which they agreed to pay a combined $6 million to resolve allegations that the two "charities" *routinely* engaged in precisely the type of conduct that is the subject of this complaint.[159]

528. As stated by the DOJ:

- "CDF and PANF worked with various pharmaceutical companies to design and operate certain funds that funneled money from the companies to patients taking the specific drugs the companies sold. These schemes enabled the pharmaceutical companies to ensure that Medicare patients did not consider the high costs that the companies charged for their drugs. The schemes also minimized the possibility that the companies' money would go to patients taking competing drugs made by other companies."

- "CDF and PANF functioned not as independent charities, but as pass-throughs for specific pharmaceutical companies to pay kickbacks to Medicare patients taking their drugs…. As a result, CDF and PANF enabled their 'donors' (the pharmaceutical companies) to undermine the Medicare program at the expense of American taxpayers."

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[157] Dr. Hay Report, pp 71-72; SeekingAlpha Article.
[158] Dr. Hay Report, pp 70-73.
[159] *See* DOJ, *Foundations Resolve Allegations of Enabling Pharmaceutical Companies to Pay Kickbacks to Medicare Patients*, (Oct. 25, 2019) https://www.justice.gov/usao-ma/pr/foundations-resolve-allegations-enabling-pharmaceutical-companies-pay-kickbacks-medicare; **Ex. P** – CDF Settlement Agreement; **Ex. Q** – PANF Settlement Agreement.

- "Both the Chronic Disease Fund and the Patient Access Network used their status as charities to shield the illegal activities of pharmaceutical companies seeking to maximize profits."[160]

529. Thus, the DOJ's investigation revealed that CDF and PANF did not operate as independent charities, but instead acted as conduits for Celgene to increase the dispensed quantities and prices of Thalomid and Revlimid.[161]

530. On December 19, 2007, the OIG issued OIG Advisory Opinion No. 07-18 to PANF. **Ex. R** – 2007 PANF Advisory Opinion.

531. The OIG modified the 2007 PANF Advisory Opinion on October 11, 2011, permitting PANF to move towards a specialty therapeutics model. **Ex. S** – 2011 Modified PANF Advisory Opinion.

532. On October 26, 2015, the OIG issued its Notice of Modification of OIG Advisory Opinion No. 07-18. **Ex. T** – 2015 Modified PANF Advisory Opinion.

533. The Modified PANF Advisory Opinion noted that in 2007, the OIG's Advisory Opinion was "a favorable opinion regarding the Charity's operation of a PAP that provides cost-sharing assistance primarily for high-cost medications to patients who have been diagnosed with one of the disease states for which the Charity maintains a disease fund and who meet certain financial need criteria."

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[160] *Id.*

[161] Celgene also settled a *qui tam* matter that included allegations of damages caused by CDF's, PANF's and Celgene's scheme alleged herein. *U.S. et al. v. Celgene Corp.*, Case No. CV 10-3165 GHK (N.D. Cal.); *see also* Dr. Hay Report pp 67-73 (setting forth the damages caused by Defendants' scheme in *U.S. et al. v. Celgene*.); *see also* DOJ, *Celgene Agrees to Pay $280 Million to Resolve Fraud Allegations Related to Promotion of Cancer Drugs For Uses Not Approved by FDA*, (Jul. 24, 2017) https://www.justice.gov/usao-cdca/pr/celgene-agrees-pay-280-million-resolve-fraud-allegations-related-promotion-cancer-drugs.

534. In May 2014, the OIG sent PANF a letter noting that the 2011 PANF Advisory Opinion "approved certain features that [the OIG] have since determined are problematic." **Ex. U** – 2014 PANF Letter.

535. The OIG proposed certifications to address the "problematic" features to PANF.

536. PANF responded to OIG's request and provided several certifications, including that "[PANF] determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner." **Ex. T** – 2015 Modified PANF Advisory Opinion.

537. As part of PANF's Charity Settlement, PANF entered into an Integrity Agreement ("IA") which noted that, in consideration of settling the claims involved in the DOJ settlement, "OIG agrees it will not rescind or terminate [the 2007 PANF Advisory Opinion]." **Ex. V –** PANF Integrity Agreement.

538. Although PANF was required to enter into an IA with the DOJ, this option was permitted rather than the DOJ issuing a full rescission of the Advisory Opinions it issued before to PANF.

539. In 2006, the OIG issued Advisory Opinion 06-10 to CDF. **Ex. W** – 2006 CDF Advisory Opinion. That advisory opinion was modified in 2015. **Ex. X** – 2015 Modified CDF Advisory Opinion.

540. The 2006 CDF Advisory Opinion stated "based on [CDF's] certifications, [CDF] provides assistance based upon a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner." **Ex. W** – 2006 CDF Advisory Opinion

541. On October 26, 2015, the OIG issued its modification of the 2006 CDF Advisory Opinion. **Ex. X** – 2015 Modified CDF Advisory Opinion. The Modification of the CDF Advisory

Opinion noted that the OIG: "asked [CDF] to certify, and it did certify, that it determines eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied for in a consistent manner."

542. CDF entered into an integrity agreement as part of their settlement with the DOJ. **Ex. Y** – CDF Integrity Agreement. That settlement agreement noted: "In consideration of the obligations of [CDF] set forth in this IA and the Settlement Agreement referenced above, OIG agrees it will not rescind or terminate Advisory Opinion 06-10, as modified, based on the Covered Conduct resolved through the Settlement Agreement."

543. Although CDF was required to enter into an IA with the DOJ, this option was permitted rather than the DOJ issuing a full rescission of the Advisory Opinions it issued before to CDF.

544. In public SEC Form 10-k (annual report) filings since their 2007 report, Celgene falsely and/or deceptively reported "donations to independent non-profit Patient Assistance organizations in the United States" as among its overall "Selling, General and Administrative expenses." In 2017, for example, Celgene reported an "increase of $70 million in donations to independent non-profit Patient Assistance organizations in the U.S." [162]; in 2012, a "$72.0 million increase in donations" [163]; in 2011, an "$11.7 million increase in donations" [164]; in 2008, an

[162] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2017*, p 44 (Feb. 7, 2018) ("2017 Celgene 10-K") (attached hereto as **Ex. O** – Excerpts of Celgene 10-K Reports).
[163] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2012*, p 64 (Feb. 15, 2013) ("2012 Celgene 10-K") (attached hereto as **Ex. O** - Excerpts of Celgene 10-K Reports).
[164] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2011*, p 61 (Feb. 22, 2012) ("2011 Celgene 10-K") **Ex. O** - Excerpts of Celgene 10-K Reports.

"increase in donations . . . of $13.3 million" [165]; and in 2007, "[d]onations to non-profit foundations that assist patients with their co-payments also increased" as compared to 2006.[166]

545. By 2019, the price of a single dose of Revlimid cost $719.82—nearly a 300% increase over the cost of the drug from 2007. A single year supply of Revlimid can now cost nearly $200,000.[167]

546. Celgene's unlawful bribes were designed to cause and did in fact result in the submission of false and misleading claims for reimbursement of the costs of Revlimid and Thalomid as submitted to both Medicare and private insurance plans, including Assignors and the Class Members.

547. Celgene further benefited from this illegal scheme by claiming tax deductions for its alleged "donations" to CDF and PANF. It did so despite the fact that the payments were in fact not made for a charitable purpose, but were designed to maintain Celgene's increasing prices, revenues, and profits on Revlimid and Thalomid.[168]

548. The information alleged in this section was not, and could not have been, reasonably known or discovered by Plaintiffs until at least late July 2016, when some such facts were first publicly reported. Around the same time (July 28, 2016), Celgene also first disclosed in an SEC Quarterly Report that it had received a subpoena from the U.S. Department of Justice

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[165] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2008*, p 45 (Feb. 17, 2009) ("2008 Celgene 10-K") **Ex. O** - Excerpts of Celgene 10-K Reports.
[166] 2007 Celgene 10-K at p 40. **Ex. O** - Excerpts of Celgene 10-K Reports.
[167] *Celgene Hikes Price of Popular Cancer Drug Revlimid*, WASHINGTON POST, (Jan. 4, 2019) https://www.washingtonpost.com/business/economy/celgene-hikes-price-of-popular-cancer-drug-revlimid/2019/01/04/01d83628-102c-11e9-8938-5898adc28fa2_story.html.
[168] Congressional Revlimid Report, pp 35-36; Dr. Hay Report.

concerning its relationships with charities that cover patients' expenses for the company's high-priced drugs.[169]

549. In addition, Celgene intentionally and fraudulently concealed its scheme, covering up the true nature of its payments and relationship with charities—including by its pattern and practice since as early as 2007 of publicly reporting and characterizing its payments as "donations" for the benefit of "independent" charities that provide co-payment assistance (including in its public financial statements)—while the payments were in fact kickbacks and/or for the purpose of using the foundations as conduits to effectuate its goals of artificially and deceptively inflating the drug prices and increasing the use of the drugs to increase profits at the expense of healthcare payors like Assignors and the Class Members. Celgene's concealment prevented Plaintiffs from reasonably discovering the facts underlying Celgene's schemes which caused Assignors' and the Class Members' injuries.

550. Through their scheme, Celgene caused pharmacies to seek reimbursement from federal health care programs for their purchases of Thalomid and Revlimid. The act of submitting claims for reimbursement carries with it an implied certification of compliance with governing federal rules that are a precondition of or material to payment. Pharmacies submitting claims for reimbursement therefore implied that the claims complied with federal law, including the AKS.

551. However, because of Celgene using CDF and PANF as conduits, they did not act as independent charities and instead acted in violation of the AKS. Therefore, those certifications were false.

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[169] Celgene Corporation, *Form 10-K Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934, for the Fiscal Year Ended December 31, 2016*, p 114 (Feb. 10, 2017) ("2016 Celgene 10-K"). **Ex. O** - Excerpts of Celgene 10-K Reports.

552. As a result of Celgene colluding with CDF and PANF to use these charities as a conduit as alleged herein, Assignors and the Class Members were harmed by paying for an increased number of prescriptions of Thalomid and Revlimid throughout the United States as a direct result of the Co-payment Circumvention Enterprise and by paying artificially increased prices for all prescriptions of Thalomid and Revlimid regardless of the charities' roles.

XIV. RICO CLASS ALLEGATIONS.

553. At all material times, Thalomid and Revlimid—manufactured and sold by Celgene—were shipped across state lines and sold to customers located both within and outside its state of manufacture.

554. During the relevant time period, in connection with the purchase and sale of Thalomid and Revlimid, monies as well as contracts, bills, and other forms of business communication and transactions, were transmitted in continuous and uninterrupted flow across state lines.

555. During the relevant time period, various methods of communication were used to effectuate the illegal acts alleged herein, including the United States mail, interstate and foreign travel, and interstate and foreign telephone commerce. The activities of Defendants, as alleged in this Amended Complaint, were within the flow of, and have substantially affected, interstate commerce.

556. Plaintiffs bring this action on behalf of themselves and the following classes:

Federal RICO / State RICO / State Consumer Protection Statute Class 1:

> All Medicare Advantage Organizations and at-risk, first-tier, and downstream entities in the United States and its territories that from January 1, 2007 through present, pursuant to Medicare contracts offering Medicare benefits, provided services, purchased the subject pharmaceuticals, provided reimbursement, or possess the recovery rights to reimbursement for some or all of the purchase price of

> Thalomid and Revlimid resulting from CDF's or PANF's co-payment assistance. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.

Federal RICO / State RICO / State Consumer Protection Statute Class 2:

> All self-funded, third-party payors and related entities in the United States and its territories that from January 1, 2007 through present, provided services, purchased the subject pharmaceuticals, provided reimbursement, or possess the recovery rights to reimbursement for some or all ofthe purchase price of Thalomid and Revlimid resulting from CDF's or PANF's co-payment assistance. This class excludes: (a) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (b) the federal government; and (c) any judges or justices involved in this action and any members of their immediate families.

557. Plaintiffs bring this action pursuant to Federal Rule of Civil Procedure 23 both individually and on behalf of a national damages class.

558. Celgene's scheme resulted in increased sales of Thalomid and Revlimid, the cost of which were borne by Assignors and the Class Members. The damages suffered by Assignors apply to all individual Class Members (and Plaintiffs as the rightful assignees of those organizations that assigned their rights to Plaintiffs). Class action law has long recognized that, when companies engage in conduct that has uniformly harmed a large number of claimants such as Assignors and other third-party payers, class resolution is an effective tool to redress the harm.

559. Assignors and the Class Members have been deprived of property and money by being caused to pay for prescriptions of Thalomid and Revlimid due to and as a result of Defendants causing the Assignors and the Class Members to pay for the drugs that they otherwise would not have had to without the Defendants' scheme and engagement in the anticompetitive and racketeering activities alleged throughout this Amended Complaint.

560. The Classes, defined above, are properly brought and should be maintained as a

nationwide class action under Rule 23(a), satisfying the class action prerequisites of numerosity, commonality, typicality, and adequacy:

> Numerosity: There are hundreds of entities (including the organizations that assigned their rights to Plaintiffs) throughout the United States whose payment for Thalomid and Revlimid were caused by Defendants' scheme. Thus, the numerosity element for class certification is met.
>
> Commonality: Questions of law or fact are common to all members of the Classes. Defendants' co-payment assistance conspiracy scheme and racketeering activity carried out by their enterprise have a common, adverse effect on all Class Members. Defendants' misconduct was directed at all members of these Classes. Defendants' unlawful co-payment assistance conspiracy scheme and racketeering activity carried out by their enterprise had a common, adverse effect on all purchasers of Thalomid and Revlimid who paid for the drugs because of Defendants' scheme. Therefore, common questions of law or fact are prevalent throughout the classes, *i.e.*, whether Defendants engaged in a pattern of racketeering activity and conspired to induce Class Members' payment for Thalomid and Revlimid prescriptions. Each Class Member shares the same needed remedy, *i.e.*, reimbursement for unlawfully paid bills and lost money or disgorgement of Defendants' profits as a result of Defendants' co-payment assistance conspiracy scheme and racketeering activity that caused Assignors and Class Members to pay for Thalomid and Revlimid.
>
> Typicality: Plaintiffs' claims are typical of the claims of the Classes because their claims arise from the same course of conduct by Defendants, *i.e.*, Defendants' formation of their co-payment scheme and racketeering activity unlawfully causing Class Members' submission of bills for payment for Thalomid and Revlimid and actual payment that would otherwise not have been made but for Defendants' conduct. Plaintiffs'claims are, therefore, typical of the Classes.
>
> Adequacy: Plaintiffs will fairly and adequately represent and protect the interests of the Classes. Plaintiffs' interests in vindicating these claims are shared with all members of the Classes. In addition, Plaintiffs are represented by competent and experienced counsel in class action litigation.

561. The Classes are properly brought and should be maintained as a class action under

Rule 23(b) because a class action is the superior method for resolving these claims. Pursuant to Rule 23(b)(3), common issues of law and fact predominate over any questions affecting only individual members of the Classes. Defendants deliberately conspired to cause Assignors to pay for Thalomid and Revlimid through the formation of their co-payment scheme that subsequently resulted in the submission and payment of Thalomid and Revlimid by Assignors and the Class Members that otherwise would not have been paid.

562. Assignors and the Class Members paid for prescriptions of Thalomid and Revlimid that they otherwise would not have paid but for Defendants' Co-payment Circumvention Enterprise and racketeering activity.

563. Members of the Classes are so numerous that joinder is impracticable. Plaintiffs believe the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

564. Plaintiffs' claims are typical of the claims of the members of the Classes. Plaintiffs and all members of the Classes were damaged by the same wrongful conduct by Defendants, i.e., they paid supra-competitive prices for and the induced over-prescription of Thalomid and Revlimid.

565. Plaintiffs will fairly and adequately protect and represent the interests of the Classes. Plaintiffs' interests are coincident with, and not antagonistic to, those of the Classes.

566. Plaintiffs are represented by counsel who are experienced and competent in the prosecution of class action antitrust litigation and have particular experience with class action antitrust litigation in the pharmaceutical industry.

567. Questions of law and fact common to the members of the Classes predominate over questions, if any, that may affect only individual class members because Defendants acted on

grounds generally applicable to the entire class. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

568. Additional questions of law and fact common to some or all the Classes include:

a. Whether Defendants engaged in a kickback scheme and thereby violated the AKS, the Travel Act, and Mail Fraud and Wire Fraud statutes;

b. The effect of such kickback scheme on the volume and sales of Thalomid and Revlimid; and

c. The quantum of overcharges paid by the Classes in the aggregate.

569. Class action treatment is a superior method for the fair and efficient adjudication of the controversy in that, among other things, such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, and expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities with a method for obtaining redress on claims that might not be practicable to pursue individually, substantially outweigh any difficulties that may arise in management of this class action.

570. Plaintiffs know of no difficulty to be encountered in this action that would preclude its maintenance as a class action.

XV. TOLLING OF THE STATUTE OF LIMITATIONS.

Class Action Tolling

571. The claims asserted in this Amended Complaint have been tolled as a matter of law by the pendency of various class actions, as to which Assignors were putative class members,

alleging antitrust violations related to the actions by Defendants concerning Thalomid and Revlimid.[170]

Fraudulent Concealment Tolling

572. The claims asserted in this Amended Complaint have been tolled as a matter of law as Defendants took affirmative steps to conceal the wrongful conduct alleged herein including, *inter alia*, concealing their invalid patents through the use of sham citizen petitions and wholly improper patent litigation against generic manufacturers.

Discovery Rule Tolling

573. Assignors had no way of knowing about Defendants' schemes alleged herein. Within the applicable statutes of limitation, Assignors could not have discovered through the exercise of reasonable diligence that Defendants were concealing the conduct complained of herein. Assignors did not discover, and did not know of, facts that would have caused a reasonable person to suspect, that the Defendants were engaged in the schemes alleged herein, nor would a reasonable diligent investigation have disclosed the true facts.

Continuing Violation Doctrine

574. This Amended Complaint alleges a continuing course of conduct (including conduct within the limitations periods), and Defendants' unlawful conduct has inflicted continuing and accumulating harm within the applicable statutes of limitations. Thus, Plaintiffs can recover for damages that they suffered during any applicable limitations period.

XVI. CLAIMS FOR RELIEF

FIRST CLAIM OF RELIEF
Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Celgene's Violations of Section 2 of the Sherman Act

[170] *See, inter alia, International Union of Bricklayers and Allied Craft Workers Local 1 Health Fund v. Celgene Corporation*, Case no. 2:14-cv-06997 (D.N.J., November 7, 2014). Further, Plaintiffs timely excluded themselves from the certified settlement class of end payor plaintiffs.

Against Celgene [171]

575. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as though set forth at length herein.

576. Celgene knowingly, intentionally, and cooperatively engaged in an anticompetitive scheme designed to delay and block entry of AB-rated generic equivalents of Thalomid and Revlimid. Celgene injured Assignors through this conduct.

577. Had manufacturers of generic Revlimid and generic Thalomid entered the market and lawfully competed with Celgene, Assignors would have substituted lower-priced generic Revlimid and generic Thalomid for the higher-priced brand-named drugs for most of their purchases.

578. Assignors have suffered harm and will continue to suffer harm in the future as a result of paying higher prices for Revlimid and Thalomid than they would have absent Celgene's continuing anticompetitive conduct.

579. Assignors' allegations described herein comprise violations of Section 2 of the Sherman Act, as well as state laws.

580. Assignors overpaid for substantial amounts of Revlimid and Thalomid between at least 2010 and the present.

581. Plaintiffs seek a declaratory judgment under Federal Rule of Civil Procedure 57 and 28 U.S.C. § 2201(a) ruling that Celgene's conduct violates Section 2 of the Sherman Act.

582. Plaintiffs also seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15. U.S.C. § 26, and other applicable law, to correct for the anticompetitive market

[171] Again, for purposes of this Complaint, any reference to Celgene is be considered synonymous with a reference to Bristol Myers Squibb. Likewise, any claim asserted against Celgene is to be similarly construed as a clam against Bristol Myers Squibb.

effects caused by Celgene's unlawful conduct and other relief to assure that similar anticompetitive conduct does not occur.

SECOND CLAIM OF RELIEF
Violation of Racketeering Influence Corrupt Organization Act ("RICO") 18 U.S.C. § 1962(c) Through the Use of the Co-Payment Charity Scheme
Against All Defendants

583. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as if fully set forth herein.

584. At all relevant times, Defendants were "persons" under 18 U.S.C. § 1961(3) who conducted the affairs of the enterprise through the pattern of racketeering activity detailed throughout this Amended Complaint in violation of 18 U.S.C. § 1962(c).

585. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c).

586. 18 U.S.C. 1964(c) provides that "[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue . . . and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee."

587. The elements of a RICO claim for a violation of § 1962(c) are: (i) conduct; (ii) of an enterprise; (iii) through a pattern of; (iv) racketeering activity.

Description of the Co-Payment Circumvention Enterprise

588. RICO defines an enterprise as "any individual, partnership, corporation, association, or other legal entity, and any union group or individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4).

589. Under 18 U.S.C. § 1961(4), a RICO "Enterprise" may be an association-in-fact that, although it has no formal structure, has (i) a common purpose, (ii) relationships among those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprises' purpose.

590. The Co-Payment Circumvention Enterprise is an association-in-fact enterprise within the meaning of 18 U.S.C. § 1961(4), consisting of Defendants Celgene, CDF, and PANF, including their directors, officers, employees, and agents.

591. The Co-Payment Circumvention Enterprise functioned as an ongoing and continuing unit. The Co-Payment Circumvention Enterprise was created and/or used as a tool to effectuate a pattern of racketeering activity. Each of the Enterprise participants is a "person" distinct from the Enterprise.

592. The Co-Payment Circumvention Enterprise had a common purpose that united its members. This purpose was to profit from the illegal kickbacks and referrals. The common purpose was accomplished by (1) growing CDF's and PANF's co-payment assistance fund and Celgene's executive salaries and (2) by increasing the number of patients who had their drugs purchased by Assignors, thereby increasing the amount of money Celgene made from Revlimid and Thalomid. By funneling and steering people into utilizing CDF and PANF's co-payment assistance fund, the Co-Payment Circumvention Enterprise increased Celgene's number of covered "customers," thereby triggering Assignors' coverage obligations for their Enrollees and eliminating price sensitivity to Thalomid and Revlimid. These two prongs of the plan worked hand-in-hand, resulting in a vicious cycle that expanded profits for CDF, PANF, and Celgene, at the cost to Assignors and other health plans, and Celgene "customers."

593. Each of the Defendants received substantial revenue from participating in the Co-Payment Circumvention Enterprise. Such revenue was exponentially greater than it would have

been in the absence of such Enterprise. Each portion of the Enterprise benefitted as intended from the existence of the other parts.

594. The Co-Payment Circumvention Enterprise has a systemic linkage because there are contractual relationships, financial ties, and continuing coordination of activities between each Defendant.

595. There were interpersonal relationships between those associated with the Co-Payment Circumvention Enterprise. This includes relationships (1) among CDF's and PANF's officers and directors and relationships among Celgene's officers, directors, principals, and agents; and (2) relationships between CDF, PANF, and Celgene. This is evidenced by Celgene routinely communicating (through the US Mail and Wire) with the charities to assure that its "donations" were sufficient to keep funds flowing towards potential users of Celgene drugs and drive its profits. CDF and PANF settled with the DOJ involving the exact kind of conduct at issue here, noting that CDF and PANF operated not as independent charities, but as pass-throughs for specific pharmaceutical companies, for example, to pay kickbacks, enabling pharmaceutical companies to undermine the Medicare program at the expense of American taxpayers, *inter alia*. This conduct shows that CDF, PANF, and Celgene communicated information important to their scheme *through the mail and wires* to profit illegally, and that they had a relationship.

596. The Co-Payment Circumvention Enterprise had the longevity sufficient to permit its associates to pursue the enterprise's purpose. It lasted for years, during which time its purposes were pursued. Since 2007, Celgene increased the amount of "donations" they made to "independent" charities, and Celgene continued to increase their executive compensation. Celgene further insulated the price sensitivity of Thalomid and Revlimid, as demonstrated by the 255% increase in price of Revlimid since launch. Celgene also used anticompetitive and illegal tactics to

increase the number of "customers" buying Thalomid and Revlimid, allowing Celgene to further increase its profits.

597. Celgene carried out its business activities both with CDF and without CDF, including marketing and selling Thalomid and Revlimid to other entities beside CDF.

598. Celgene carried out its business activities both with PANF and without PANF, including marketing and selling Thalomid and Revlimid to other entities beside PANF.

599. Moreover, CDF and PANF carried out their business activities both with Celgene and without Celgene, as evidenced by the fact that they settled allegations involving the same conduct alleged here with other pharmaceutical companies.

Conduct of the Enterprise's Affairs

600. Each Defendant conducted or participated in, either directly or indirectly, the conduct of the Co-Payment Circumvention Enterprise's affairs. Each Defendant was associated with the Co-Payment Circumvention Enterprise and each operated and managed the Co-Payment Circumvention Enterprise. Such participation included, but is not limited to: (1) CDF and PANF shared data (through the US mail and wire) so CDF, PANF, and Celgene could effectively conduct ROI analyses on the amounts of Celgene's "donations"; (2) Celgene providing necessary "donations" for the co-payments, thus triggering the payment obligations of Assignors; and (3) CDF, PANF, and Celgene steered and funneled patients into utilizing Celgene's co-payment assistance program.

601. At all relevant times, each Defendant had been aware of the Co-Payment Circumvention Enterprise's conduct and has been a knowing and willing participant in the racketeering conduct of the Enterprise.

Defendants' Pattern of Racketeering Activity

602. To carry out, or attempt to carry out, their illegal scheme, Defendants knowingly conducted or participated, directly or indirectly, in the affairs of the Co-Payment Circumvention Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1952 (Travel Act), § 1341 (mail fraud) and § 1343 (wire fraud).

603. Defendants' pattern of racketeering likely involved thousands, if not hundreds of thousands, of separate instances of use of the U.S. mail or interstate wire facilities in furtherance of the Co-Payment Circumvention Enterprise. Each of these mailings and interstate wire transmissions constitutes an instance "racketeering activity" within the meaning of 18 U.S.C. § 1961(1)(B). Collectively, these violations constitute a "pattern of racketeering activity," within the meaning of 18 U.S.C. § 1961(5), to advance Defendants' intentional and illegal scheme.

604. As set forth throughout this Amended Complaint, Defendants engaged in an illegal scheme to harm third-party payors, including the Assignors. They funneled and steered patients into Celgene's co-payment assistance program, knowing third-party payors such as the Assignors would ultimately bear the cost of the drugs. Defendants knew their scheme to funnel, steer, and refer were violative of federal and state laws including, but not limited to, the AKS and the FCA and that they were transmitting bribes and false information through mail and wire communications.

605. Defendants' use of the mails and wires to perpetuate their Co-Payment Circumvention Enterprise involved thousands of communications which involved, among others, the following:

a. Communications from Celgene, CDF, and PANF to patients, steering them to Celgene's co-payment assistance program utilizing CDF and PANF;

b. Transmittal of bribes, disguised as donations, by Celgene to CDF so that CDF could pay the co-payments of Celgene's "customers" in Celgene's co-pay assistance program;
c. Transmittal of bribes, disguised as donations, by Celgene to PANF so that PANF could pay the co-payments of Celgene's "customers" in Celgene's co-pay assistance program;
d. Submissions of data from CDF to Celgene so that Celgene could conduct ROI analyses on its "donations" to CDF and to see how much more money it could make by increasing its "donations";
e. Submissions of data from PANF to Celgene so that Celgene could conduct ROI analyses on its "donations" to PANF and to see how much more money it could make by increasing its "donations";
f. Certifications from CDF that it would determine eligibility according to a reasonable, verifiable and uniform measure of financial need that is applied for in a consistent manner"[172];
g. Certifications from PANF that it would determine "eligibility according to a reasonable, verifiable, and uniform measure of financial need that is applied in a consistent manner";[173] and
h. Causing false claims, in violation of the FCA and AKS, to be submitted by pharmacies to Assignors.

606. The predicate acts of the Travel Act, as well as mail and wire fraud had the same purpose; that is, to make money by growing Celgene's co-pay assistance program as large as possible so CDF's and PANF's officers and directors could justify increasing their compensation and that Celgene could get as many "customers" for Revlimid and Thalomid as possible, at the expense of the Assignors and the Class Members. All the predicate acts detailed above, including the certifications made by Celgene, PANF, and CDF, as well as the wire communications in furtherance of their scheme, were for this purpose. If CDF and PANF had not falsely certified that they used uniform measures of financial eligibility and if Celgene, CDF, and PANF had not deceptively caused pharmacies to provide false bills for payment to third-party payers, Assignors and the Class Members would not have purchased Celgene's products. Defendants caused

[172] Exhibit N – Modified OIG Advisory Opinion to CDF.
[173] Exhibit M – 2015 OIG Modified PANF Advisory Opinion.

pharmacies to send false bills for payment over the mail and wire so Celgene could make larger donations to CDF and PANF, and therefore cause damage to Assignors and the Class Members.

607. These predicate acts allowed the continuance of the scheme to increase prescriptions for Thalomid and Revlimid. As a result, Assignors and the Class Members paid increased claims for prescriptions where CDF or PANF made the co-payment.

608. Celgene, CDF, and PANF, including officers, directors, agents, and principals of each organization, participated in all of the predicate acts. These individuals sent, or caused to be sent, all of the false certifications through the mails. They are the ones who communicated among one another and others in furtherance of the scheme.

609. The illegal scheme orchestrated by Defendants' Co-Payment Circumvention Enterprise injured Assignors and the Class Members.

610. The violations of the Travel Act and mail and wire fraud included transmission of false claims and the unlawful transmission of data and communications to further the racketeering scheme over a period of at least five years involving harm to multiple parties.

611. Additionally, CDF and PANF were involved in similar illegal schemes with other drug manufacturers. CDF was engaged in similar schemes with five other pharmaceutical companies: Novartis, Dendreon, Astellas, Onyx, and Questcor, enabling those companies to pay kickbacks. PANF allowed four pharmaceutical companies: Bayer, Astellas, Dendreon, and Amgen to utilize PANF as a conduit to pay kickbacks. CDF and PANF settled these claims with the U.S. Attorney's Office, with CDF agreeing to pay $2 million and PANF agreeing to pay $4 million to resolve the claims. CDF's and PANF's multi-faceted scheme involved multiple victims and predicate acts and is the exact type of broad and persistent racketeering activity that RICO was intended to stop.

612. The Co-Payment Circumvention Enterprise's illegal scheme and its predicate acts proximately caused injury to Assignors' and the Class Members' business and property by triggering the Assignors' and the Class Members' duty to purchase Thalomid and Revlimid. Defendants' predicate acts directly led to Assignors' buying Thalomid and Revlimid for their Enrollees utilizing Celgene's co-pay assistance program. Assignors and the Class Members were the direct and intended victims of the Co-payment Circumvention Enterprise.

613. Accordingly, Defendants' violations of 18 U.S.C. § 1962(c) have directly and proximately caused injuries and damages to Assignors and the Class Members. Assignors and the Class Members were harmed by paying for an increased number of prescriptions of Thalomid and Revlimid as a direct result of the co-payment enterprise. Assignors and the Class Members suffered the natural consequence of paying increased prices for those prescriptions due to Celgene recouping its "donations" to CDF and PANF for all prescriptions of Thalomid and Revlimid. Defendants' actions entitle Plaintiffs to bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(c).

THIRD CLAIM OF RELIEF
Violation of RICO 18 U.S.C. § 1962(d) Through the Co-Payment Circumvention Enterprise
Against All Defendants

614. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Second Amended Complaint as though set forth at length herein.

615. Section 1962(d) makes it unlawful for "any person to conspire to violate" section 1962(c), among other provisions.

616. Defendants violated § 1962(d) by conspiring to violate § 1962(c). The object of this conspiracy was to conduct or participate in, directly or indirectly, the conduct of the affairs of the

Co-Payment Circumvention Enterprise described previously, through a pattern of racketeering activity.

617. 18 U.S.C. 1964(c) provides that "[a]ny person injured in his business or property by reason of a violation of section 1962 of this chapter may sue . . . and shall recover threefold the damages he sustains and the cost of the suit, including a reasonable attorney's fee . . . ."

618. Celgene knowingly agreed with CDF and PANF that Celgene would perform services that would facilitate the activities of the Co-Payment Circumvention Enterprise and those who were running it in an illegal manner. Some of the services Celgene performed were steering people towards CDF's and PANF's co-payment assistance programs. Celgene also provided CDF and PANF with "donations" so the charities could pay the co-payments of Celgene's "customers" utilizing the co-payment assistance programs. Celgene also used data provided by CDF and PANF, in violation of the AKS and FCA, to determine how much money it was making from its "donations" and how much *more* money it could make by increases to its "donations." Such coordinated exchange of data shows that Celgene and CDF and Celgene and PANF were not engaged in parallel conduct but were instead working together and had a meeting of the minds on how Celgene and CDF and Celgene and PANF could both profit from the Co-Payment Circumvention Enterprise. The shared data allowed Celgene to perform ROI analyses on the "donations" to CDF and PANF how much more money it could make by increasing its "donations." Celgene thus set out a roadmap of illegal activities and profits. Celgene, CDF, and PANF also caused false certifications to be sent over the interstate mails and wires claiming they were in compliance with federal law, including the AKS and FCA.

619. Further, CDF and PANF, separately, both knowingly agreed with Celgene that they would perform services that would facilitate the activities of the Co-Payment Circumvention

Enterprise and those who were running it in an illegal manner. Some of the services that CDF and PANF each separately performed were steering people towards each of their co-payment assistance programs. CDF and PANF each separately caused certifications to be sent over the interstate mails and wires claiming they were in compliance with federal law, including the AKS and FCA. CDF and PANF each provided certifications that they would determine eligibility utilizing a uniform measure of financial need that is applied in a consistent manner. CDF and PANF each sent Celgene data, in violation of the AKS and FCA, so Celgene could see how much money it was making from its "donations" to CDF and PANF, and how much more money it could make by increasing its "donations." Indeed, this conduct shows that Celgene and CDF and Celgene and PANF did not engage in parallel conduct but instead worked together and had a meeting of the minds that they could each profit from the Co-payment Circumvention Enterprise. CDF and PANF both knew that if Celgene provided more "donations", Celgene would make more money. Thus, by illegally providing data to Celgene, the charities were soliciting greater contributions.

620. Celgene knowingly agreed with CDF that one or both of them would commit at least two instances of Travel Act violations or of mail and wire fraud (or cause an innocent third-party to send false statements over the mails and wires). In short, Celgene knew that it and CDF had to abide by the AKS and FCA, and it knew the scheme it was engaged in or was going to engage in with CDF was going to violate these statutes. It also knew that each time a pharmacy filled a prescription for someone utilizing CDF's co-pay assistance, any certifications the pharmacist made that he or she would abide by federal law would be false.

621. Celgene knowingly agreed with PANF that one or both of them would commit at least two instances of Travel Act violations or of mail and wire fraud (or cause an innocent third-party to send false statements over the mails and wires). In short, Celgene knew that it and PANF

had to abide by the AKS and FCA, and it knew the scheme it was engaged in or was going to engage in with PANF was going to violate those statutes. It also knew that each time a pharmacy filled a prescription for someone utilizing PANF's co-pay assistance, any certifications the pharmacist made that he or she would abide by federal law would be false.

622. CDF knowingly agreed with Celgene that one or both of them would commit at least two instances of Travel Act violations or of mail and wire fraud (or cause an innocent third-party to send false statements over the mails and wires). In short, CDF knew it and Celgene had to abide by the AKS and FCA, and it knew the scheme it was engaged in or was going to engage in with Celgene was going to violate both statutes. It also knew that each time a pharmacy filled a prescription for someone utilizing its co-pay assistance, any certifications the pharmacist made that he or she would abide by federal law would be false.

623. PANF knowingly agreed with Celgene that one or both of them would commit at least two instances of Travel Act violations or of mail and wire fraud (or cause an innocent third-party to send false statements over the mails and wires). In short, PANF knew it and Celgene had to abide by the AKS and FCA, and it knew the scheme it was engaged in or was going to engage in with Celgene was going to violate those statutes. It also knew that each time a pharmacy filled a prescription for someone utilizing its co-pay assistance, any certifications the pharmacist made that he or she would abide by federal law would be false.

624. Defendants all knew that any communications they had over the telephone, email, or text message in furtherance of the scheme would be predicate acts.

625. In short, Celgene and CDF and Celgene and PANF knowingly agreed to pursue the same objective of profiting illegally from the Co-payment Circumvention Enterprise. They agreed to divide the work of accomplishing this objective. Celgene would make the bribes; the charities

would provide data; they would both steer patients and make false certifications. Each Defendant intended to further this endeavor, which, as described above, when completed, amounted to a violation of 18 U.S.C. § 1962(c) that proximately and directly caused injury to Assignors and the Class Members.

626. Plaintiffs bring this action for three times their actual damages, as well as injunctive/equitable relief, costs, and reasonable attorneys' fees pursuant to 18 U.S.C. § 1964(d).

FOURTH CLAIM OF RELIEF
Monopolization and Monopolistic Scheme under State Law
Against Celgene[174]

627. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as though set forth at length herein.

628. At all relevant times, Celgene, and BMS, after acquiring Celgene, possessed monopoly power in the defined relevant market since its NDAs for Thalomid and Revlimid were respectively approved. Celgene knowingly and willfully engaged in a course of exclusionary conduct designed to prevent generic manufacturers from entering the market and unlawfully extended its monopoly power.

629. Celgene intentionally extended its monopoly power in the relevant market through its anticompetitive and illegal scheme. Thus, Assignors paid artificially inflated prices for their purchases of Thalomid and Revlimid. There is and was no non-pretextual justification for Celgene's anticompetitive actions.

630. As a direct and proximate result of Celgene's conduct, as alleged herein, Assignors were injured.

631. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

[174] Claims against Celgene are synonymous with claims against BMS.

a. Cal. Bus. & Prof. Code §§ 17200, and California common law, with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, *et seq*., and Conn. Gen. Stat. § 42-110a, *et seq.*, with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts by Assignors, which paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts;

f. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165, *et seq*., with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 257, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico;

j. R.I. Gen. Laws §§ 6-36-1, *et seq*., with respect to purchases of Thalomid and Revlimid in Rhode Island; and

k. Wis. Stat. § 133.03, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin by Assignors, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Assignors paid substantially higher prices for Thalomid and Revlimid in Wisconsin.

FIFTH CLAIM FOR RELIEF
Attempted Monopolization Under State Law
Against Celgene[175]

632. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as though set forth at length herein.

[175] Claims against Celgene are synonymous with claims against BMS.

633. Celgene, through its anticompetitive scheme, and BMS, after acquiring Celgene, specifically intended to maintain monopoly power in the relevant market. It was Celgene's conscious objective to control prices and exclude competition in the relevant market.

634. The natural, intended, and foreseeable consequences of Celgene's anticompetitive scheme was to control prices and exclude competition in the relevant market, to the extent it did not succeed.

635. There is a substantial and real chance, a reasonable likelihood, and/or a dangerous probability that Celgene will succeed in and achieve its goal of maintaining monopoly power in the relevant market.

636. As a direct and proximate result of Celgene's conduct, Assignors were harmed with respect to their purchases of Thalomid and Revlimid, as explained above.

637. By engaging in the foregoing conduct, Celgene has intentionally and wrongfully attempted to monopolize the relevant market in violation of the following state laws:

a. Cal. Bus. & Prof. Code §§ 17200, *et seq*., and California common law, with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, *et seq*., and Conn. Gen. Stat. § 42-110a, *et seq*., with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 740 Ill. Comp. Stat. 10/3, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts by Assignors, which paid substantially higher prices for Thalomid and Revlimid in actions and transactions occurring substantially within Massachusetts;

f. Mich. Comp. Laws Ann. §§ 445.773, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 340, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165.01, *et seq*., and Ohio Rev. Code Ann § 1331.01, *et seq* with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 257, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico;

j. R.I. Gen. Laws §§ 6-36-1, *et seq*., with respect to purchases of Thalomid and Revlimid in Rhode Island; and

k. Wis. Stat. § 133.03, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin by Assignors, in that the actions and transactions alleged herein substantially affected and continue to affect the people of Wisconsin, whereby Assignors paid substantially higher prices for Thalomid and Revlimid in Wisconsin.

SIXTH CLAIM FOR RELIEF
Unfair and Deceptive Trade Practices Under State Law
Against All Defendants

638. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as though set forth at length herein.

639. Defendants engaged in unfair competition or unfair, unconscionable, deceptive, or fraudulent acts or practices in violation of the state consumer protection statutes listed below. As a direct and proximate result of Defendants' anticompetitive, deceptive, unfair, unconscionable, and fraudulent conduct, Assignors were deprived of the opportunity to purchase generic versions of Thalomid and Revlimid and forced to pay artificially inflated prices for these drugs.

640. There was and is a gross disparity between the price that Assignors paid and continue to pay for their direct and indirect purchases of Thalomid and Revlimid and the value received, given that a much cheaper substitute generic product should be available, and prices for Thalomid and Revlimid should be much lower, but for Celgene's unlawful scheme.

641. Further, Defendants directly misrepresented to Assignors that they were complying with federal and state laws, including laws against bribery, kickbacks, and false claims to the Government.

642. Defendants intended payers, such as Assignors, to rely on these certifications. The intention may be inferred by the very nature of the representation, whose sole purpose was to procure payment for Thalomid and Revlimid. These representations and certifications were made in an effort by Defendants to have the consuming public utilize CDF and PANF funds and were addressed to the market generally by having improper and unnecessary prescriptions for Thalomid and Revlimid paid for by Medicare and third-party payors including Assignors. The ultimate consequence of this conduct is significant injury to the consuming public by, among other things, imposing additional costs on the taxpaying public for Medicare, and third-party payors such as Health Plans.

643. Assignors relied on these misrepresentations to their detriment, which were material to their decision to pay for Thalomid and Revlimid.

644. Assignors were directly and proximately injured by Defendants' conduct, suffered an injury in fact, and suffered actual, ascertainable damages.

645. Assignors would not have reimbursed for nearly as much of Thalomid and Revlimid as they did, had Defendants refrained from engineering the false representations or otherwise disclosed their schemes.

646. By engaging in the foregoing conduct, Celgene has engaged in unfair competition or deceptive acts and practices in violation of the following state laws:

a. Cal. Bus. Code §§ 16700, *et seq*., and Cal. Bus. Code §§ 17200, *et seq*., with respect to purchases of Thalomid and Revlimid in California;

b. Conn. Gen. Stat. § 35-24, et seq., and Conn. Gen. Stat. § 42-110a, et seq., with respect to purchases of Thalomid and Revlimid in Connecticut;

c. Fla. Stat. §§ 501.201, *et seq*., with respect to purchases of Thalomid and Revlimid in Florida;

d. 815 Ill. Comp. Stat §§ 505/1, *et seq*., with respect to purchases of Thalomid and Revlimid in Illinois;

e. Mass. Gen. L. Ch. 93A, *et seq*., with respect to purchases of Thalomid and Revlimid in Massachusetts;

f. Mich. Stat. §§ 445.901, *et seq*., with respect to purchases of Thalomid and Revlimid in Michigan;

g. N.Y. Gen. Bus. Law §§ 349, *et seq*., with respect to purchases of Thalomid and Revlimid in New York;

h. Ohio Rev. Code Ann. § 4165, *et seq*., with respect to purchases of Thalomid and Revlimid in Ohio;

i. 10 L.P.R.A. § 257, *et seq*., with respect to purchases of Thalomid and Revlimid in Puerto Rico; and

j. Wis. Stat. § 100.18, Wis. Stat. § 100.20, *et seq*., with respect to purchases of Thalomid and Revlimid in Wisconsin.

SEVENTH CLAIM FOR RELIEF
Unjust Enrichment Under State Law
Against All Defendants

647. Plaintiffs re-allege and incorporate by reference paragraphs 1-574 of this Amended Complaint as though set forth at length herein.

648. Celgene, and BMS, after acquiring Celgene, has benefitted from monopoly profits on the sale of Thalomid and Revlimid resulting from the unlawful and inequitable acts alleged in this Amended Complaint.

649. Celgene's financial benefit resulting from its unlawful and inequitable acts is traceable to overpayments for direct and indirect purchases of Thalomid and Revlimid by Assignors.

650. Assignors have conferred upon Celgene an economic benefit, i.e., profits from unlawful overcharges and monopoly profits, to the economic detriment of Assignors.

651. It would be futile for Assignors to seek a remedy from any party with whom they have privity of contract with for its direct or indirect purchases of Thalomid and Revlimid.

652. It would be futile for Assignors to seek to exhaust any remedy against the immediate intermediary in the chain of distribution from which Assignors purchased Thalomid and Revlimid, as they are not liable and would not compensate Assignors for unlawful conduct caused by Celgene.

653. The economic benefit of overcharges and monopoly profits derived by Celgene through charging supra-competitive and artificially inflated prices for Thalomid and Revlimid is a direct and proximate result of Celgene's unlawful conduct.

654. The economic benefits derived by Celgene rightfully belong to Assignors, as they paid anticompetitive and monopolistic prices beginning in at least 2010 and continuing through the present, and they will continue to do so until the effects of Celgene's illegal and anticompetitive conduct cease.

655. It would be inequitable under unjust enrichment principles under the law of the District of Columbia and the laws of all states and territories in the United States, except Ohio and Indiana, for Celgene to be permitted to retain any of the overcharges for Revlimid and Thalomid derived from Celgene's unfair and unconscionable methods, acts, and trade practices alleged in this Amended Complaint.

656. Celgene is aware of and appreciates the benefits bestowed upon it by Assignors.

657. Celgene should be compelled to disgorge in a common fund for the benefit of Plaintiffs all unlawful or inequitable proceeds it received.

658. A constructive trust should be imposed upon all unlawful or inequitable sums received by Celgene traceable to Plaintiffs' Assignors.

EIGHTH CLAIM OF RELIEF
Violations of the Civil Remedies for Criminal Practices Act, Fla. Stat. 77101, *et seq.*
Against All Defendants

659. Plaintiffs re-allege and incorporate by references paragraphs 1-574 of this Amended Complaint as if fully set forth herein.

660. At all times, as set forth above, Celgene's, CDF's and PANF's actions were unlawful under Section 772.103(3), Florida Statutes, as they were all "employed by, or associated with, any enterprise through a pattern of criminal activity."

661. Celgene, CDF and PANF violated 772.101, *et seq.*, Florida Statutes by participating in or conducting the affairs of the Co-Payment Circumvention Enterprise (as described more fully above) through a pattern of racketeering activity.

662. Plaintiffs and Assignors are "persons" as defined in Section 1.01, Florida Statutes, injured in their business or property, by reason of Celgene's, CDF's, and PANF's racketeering violations.

Description of the Co-Payment Circumvention Enterprise

663. Celgene, CDF, and PANF are "persons" within the meaning of Section 1.01, Florida Statutes.

664. Celgene and CDF are members of and constitute an "association in-fact enterprise."

665. Celgene and PANF are members of and constitute an "association in-fact enterprise."

666. The Co-Payment Circumvention Enterprise is an association-in-fact of individuals and corporate entities within the meaning of Section 772.101, Florida Statutes, and consists of "persons" associated together for a common purpose.

667. The purpose of the Co-Payment Circumvention Enterprise was to maximize Celgene's profits and CDF's and PANF's executive compensation.

668. The Co-Payment Circumvention Enterprise had an ongoing organization with an ascertainable structure and functioned as a continuing unit with separate roles and responsibilities. Celgene is the source of the schemes alleged herein, including providing kickbacks to subsidize payments for Thalomid and Revlimid whose co-payments were provided by CDF and PANF.

669. For CDF's part, CDF accepted these kickbacks and provided unlawful payments for Thalomid and Revlimid.

670. For PANF's part, PANF accepted Celgene's kickbacks and provided unlawful payments for Thalomid and Revlimid.

671. Celgene and CDF, individually and collectively, fulfilled their roles in the Co-Payment Circumvention Enterprise.

672. Celgene and PANF, individually and collectively, fulfilled their roles in the Co-Payment Circumvention Enterprise.

673. Celgene and CDF were separate and distinct legal entities with distinct purposes. Celgene is the architect of the Co-Payment Circumvention Enterprise, with the sole purpose to make as much money off of Thalomid and Revlimid as possible before generic competition entered the market. For CDF, it was to raise the amount of money in the funds to justify paying higher salaries to their executives.

674. Celgene and PANF were separate and distinct legal entities with distinct purposes. Celgene is the architect of the Co-Payment Circumvention Enterprise, with the sole purpose to make as much money off of Thalomid and Revlimid as possible before generic competition entered the market. For PANF, it was to raise the amount of money in the funds to justify paying higher salaries to their executives.

675. The Co-Payment Circumvention Enterprise had an existence that was separate and distinct from the pattern of racketeering in which Celgene and CDF engaged. Specifically, Celgene and CDF conspired with each other to minimize and/or conceal the amount of information Assignors received regarding the claims for payment of Thalomid and Revlimid, materially resulting in Assignors' reimbursement of Thalomid and Revlimid purchases that they would not have otherwise paid for. *See* Section 817.234, Florida Statutes ("A person commits insurance fraud punishable as provided in subsection (11) if that person, with the intent to injure, defraud, or deceive any insurer: 1. Presents or causes to be presented any written or oral statement, as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider contract, knowing that such statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claims(.)").

676. The Co-Payment Circumvention Enterprise had an existence that was separate and distinct from the pattern of racketeering in which Celgene and PANF engaged. Specifically, Celgene and PANF conspired with each other to minimize and/or conceal the amount of information Assignors received regarding the claims for payment of Thalomid and Revlimid, materially resulting in Assignors' reimbursement of the purchase price of Thalomid and Revlimid that they would not have otherwise paid for. *See* Section 817.234, Florida Statutes ("A person commits insurance fraud punishable as provided in subsection (11) if that person, with the intent to injure, defraud, or deceive any insurer: 1. Presents or causes to be presented any written or oral statement, as part of, or in support of, a claim for payment or other benefit pursuant to an insurance policy or a health maintenance organization subscriber or provider contract, knowing that such

statement contains any false, incomplete, or misleading information concerning any fact or thing material to such claims(.)").

677. At all relevant times herein, Celgene and CDF operated, controlled, and managed the Co-Payment Circumvention Enterprise, through a variety of actions. Celgene and CDF failed to disclose a material fact regarding the existence of the kickbacks in violation of Section 817.234, Florida Statues, (i.e., Celgene and CDF causing pharmacies to submit false submissions of payments to Assignors and the Class Members.).

678. At all relevant times herein, Celgene and PANF operated, controlled, and managed the Co-Payment Circumvention Enterprise, through a variety of actions. First, PANF submitted falsely submitted the level of control that Celgene had over PANF in the PAP to the OIG on numerous occasions. Second, Celgene and PANF failed to disclose a material fact regarding the existence of the kickbacks in violation of Section 817.234, Florida Statues, (i.e., causing pharmacies to submit false submissions of payments to Assignors and the Class Members.).

679. Celgene and CDF's participation in the Co-Payment Circumvention Enterprise was necessary for the successful operation of the schemes. The members of the Co-Payment Circumvention Enterprise all served a common purpose, which was to increase the fund to an enormous size while knowing each payment was a kickback, while minimizing the amount of information Assignors, the Class Members, and the innocent third-party pharmacies, knew about the program. These affirmative acts and strategic omissions were material to Assignors' and the Class Members' decision to issue payment for Thalomid and Revlimid. The Co-Payment Circumvention Enterprise's actions maximized the revenue and profitability of the Enterprises' members by knowingly causing payments for Thalomid and Revlimid alleged herein.

680. Celgene and PANF's participation in the Co-Payment Circumvention Enterprise was necessary for the successful operation of the schemes. The members of the Co-Payment Circumvention Enterprise all served a common purpose, which was to increase the fund to an enormous size while knowing each payment was a kickback, while minimizing the amount of information Assignors, the Class Members, and the innocent third-party pharmacies, knew about the program. These affirmative acts and strategic omissions were material to Assignors' and the Class Members' decision to issue payment for Thalomid and Revlimid. The Co-Payment Circumvention Enterprise's actions maximized the revenue and profitability of the Enterprises' members by knowingly causing payments for Thalomid and Revlimid alleged herein.

681. Section 772.102, Florida Statutes, provides that criminal activity is any activity chargeable by indictment or information by amongst other statutes Section 817.234, Florida Statutes. Section 817.234, Florida Statutes, criminalizes situations where health care companies, such as Assignors and the Class Members, are provided incomplete or misleading information concerning any fact or thing material to a claim for payment. As set forth below, Celgene, CDF, and PANF have committed violations of Section 817.234, Florida Statutes, by providing incomplete or misleading information material to Assignors' and the Class Members' decision to issue payment for Thalomid and Revlimid.

682. Celgene and CDF committed numerous acts of racketeering by providing incomplete or misleading information related to Thalomid and Revlimid. Celgene and CDF knew or had reason to know that they were providing incomplete or misleading information regarding these claims.

683. Celgene and PANF committed numerous acts of racketeering by providing incomplete or misleading information related to Thalomid and Revlimid. Celgene and PANF knew

or had reason to know that they were providing incomplete or misleading information regarding these claims.

684. Celgene and CDF knew or had reason to know that they were not providing complete or non-misleading information pursuant to Section 817.234, Florida Statutes. Despite knowledge of these facts, they induced Assignors and the Class Members to make payment for claims that they otherwise would not have paid. Instead, Celgene and CDF knowingly provide incomplete information to enrich their bottom line.

685. Celgene and PANF knew or had reason to know that they were not providing complete or non-misleading information pursuant to Section 817.234, Florida Statutes. Despite knowledge of these facts, they induced Assignors and the Class Members to make payment for claims that they otherwise would not have paid. Instead, Celgene and PANF knowingly provide incomplete information to enrich their bottom line.

686. Based on these omissions, Assignors and the Class Members provided payments for Thalomid and Revlimid throughout the United States, including Florida, based on half-truths, inaccurate information, and deliberate omissions. Celgene and CDF's omissions were material to the payment of Thalomid and Revlimid that Assignors and the Class Members provided payment for. Had Assignors and the Class Members known of the Co-Payment Circumvention Enterprise, they would not have submitted payment for Thalomid and Revlimid.

687. Based on these omissions, Assignors and the Class Members provided payments for Thalomid and Revlimid throughout the United States, including Florida, based on half-truths, inaccurate information, and deliberate omissions. Celgene and PANF's omissions were material to the payment of Thalomid and Revlimid that Assignors and the Class Members provided

payment for. Had Assignors and the Class Members known of the Co-Payment Circumvention Enterprise, they would not have submitted payment for Thalomid and Revlimid.

688. Assignors and the Class Members were the primary victims of Celgene and CDF's unlawful scheme. Assignors and the Class Members paid for Thalomid and Revlimid throughout the United States, including Florida, based on Celgene and CDF's omissions of material information pursuant to Section 817.234, Florida Statutes.

689. Assignors and the Class Members were the primary victims of Celgene and PANF's unlawful scheme. Assignors and the Class Members paid for Thalomid and Revlimid throughout the United States, including Florida, based on Celgene and PANF's omissions of material information pursuant to Section 817.234, Florida Statutes.

690. As part of this scheme, Celgene and CDF caused pharmacies to submit false certifications and misled Assignors and the Class Members into reimbursing prescriptions of Thalomid and Revlimid. Celgene and CDF conducted or participated, directly or indirectly, in the Co-Payment Circumvention Enterprise through a pattern of unlawful activity.

691. As part of this scheme, Celgene and PANF caused pharmacies to submit false certifications and misled Assignors and the Class Members into reimbursing prescriptions of Thalomid and Revlimid. Celgene and PANF conducted or participated, directly or indirectly, in the Co-Payment Circumvention Enterprise through a pattern of unlawful activity.

692. By reason of and as a result of the conduct of Celgene and CDF, and in particular, their pattern of criminal activity, Assignors and the Class Members were injured in their business or property.

693. By reason of and as a result of the conduct of Celgene and PANF, and in particular, their pattern of criminal activity, Assignors and the Class Members were injured in their business or property.

694. Celgene and CDF's violations have directly and proximately caused injuries and damages to Assignors and the Class Members, and Plaintiffs have the right to bring this action for the damages alleged herein.

695. Celgene and PANF's violations have directly and proximately caused injuries and damages to Assignors and the Class Members, and Plaintiffs have the right to bring this action for the damages alleged herein.

696. Pursuant to Section 772.11, Florida Statues, Plaintiffs and the Class Members seek their reasonable attorneys' fees and costs associated with prosecution of this action.

XVII. DEMAND FOR JUDGMENT

WHEREFORE, Plaintiffs, individually and on behalf of the putative Class Members, demand judgment against Defendants as follows:

1. Awarding Plaintiffs and the Class Members actual, consequential, compensatory, statutory, treble, punitive, and/or other damages, in an amount to be proven at trial, including pre- and post- judgment interest at the statutory rates;

2. Awarding Plaintiffs and the Class Members equitable relief in the nature of disgorgement, restitution, and the creation of a constructive trust to remedy Defendants' unjust enrichment;

3. Declaring the acts alleged herein to be unlawful under the state statutes set forth above, and the common law of unjust enrichment of the states and territories set forth above and permanently enjoining Defendants from continuing their unlawful conduct;

4. Determining that this action is a proper class action, designating Plaintiffs as class representatives under Rule 23 of the Federal Rules of Civil Procedure and Plaintiffs' counsel as Class Counsel.

5. Awarding Plaintiffs and the Class Members their reasonable costs and expenses, including attorneys' fees; and

6. Awarding such other legal or equitable relief as the Court deems just and proper.

XVIII. JURY DEMAND

Plaintiffs and the Class Members demand a jury trial on all claims so triable under Federal Rule of Civil Procedure Rule 38.

Dated: May 27, 2022

Respectfully submitted,

SANTOMASSIMO DAVIS LLP

By: */s/ Anthony J. Davis*

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Appendix

Plaintiff MSPRC's Assignment to Demonstrate Standing

1. Certain series of MSPRC executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn MSPRC through its LLC Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPRC alleges the below assignment to demonstrate standing.

2. On May 12, 2017**, SummaCare, Inc. ("SMCR")** irrevocably assigned to MSP Recovery, LLC all its rights to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("SMCR Assignment"). Specifically, the SMCR Assignment states the following:

> [SMCR] hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of [SMCR]'s right, title, ownership and interests in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for [SMCR] that [SMCR] had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to [SMCR] arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims[.]"

SMCR Assignment at § 4.1.

3. On June 12, 2017, MSP Recovery, LLC irrevocably assigned all rights acquired under the SMCR Assignment to Series 16-11-509, a designated series of MSPRC ("Series 16-11-509 Assignment"):

> Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the [Assigned Claims] (and all proceeds and products thereof) as such terms are defined in the [SMCR Assignment.]

Series 16-11-509 Assignment at p.1.

4. SummaCare, Inc. consented to, acknowledged, approved, and ratified the Series 16-11-509 Assignment, which is memorialized in a letter dated September 5, 2018.

5. Consideration was given between each party in executing the SMCR Assignment and the Series 16-11-509 Assignment.

Plaintiff MSPA's Assignment Demonstrating Standing

1. MSPA was irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' Enrollees and health plan members. These assignments authorize MSPA to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MSPA alleges the below assignment to demonstrate standing.

2. On December 16, 2014, **Interamerican Medical Center Group, LLC ("IMC")** irrevocably assigned to MSP Recovery, LLC all of its rights to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("IMC Assignment"). Specifically, the IMC Assignment, states the following:

> By way of this Agreement, [IMC] appoints, directs, and, otherwise, irrevocably assigns all of [IMC's] rights as it pertains to the rights pursuant to any plan, State or Federal statute(s) whatsoever directly and/or indirectly for any of its members and/or plan participants, and/or rights pursuant to any agreement[.]

IMC Assignment at § 1.1.

3. On February 20, 2015, MSP Recovery, LLC irrevocably assigned all rights acquired under the IMC Assignment to MSPA ("MSPA Assignment 3"):

> Assignor hereby irrevocably assigns, transfers, conveys, sets over, and delivers to Assignee or its assigns any and all of Assignor's right, title, ownership and interest in and all rights and entitlements, that Assignor has, may have had, or has asserted against third parties from or relating to the Claims [assigned pursuant to the IMC Assignment].

MSPA Assignment 3 at p. 1.

4. IMC consented to, acknowledged, approved, and ratified the MSPA Assignment 3.

5. Consideration was given between each party in executing the IMC Assignment and the MSPA Assignment 3.

Plaintiff MAO-MSO's Assignment Demonstrating Standing

1. MAO-MSO has been irrevocably assigned any and all rights to recover payments made on behalf of its Assignors' Enrollees and health plan members. These assignments authorize MAO-MSO to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. MAO-MSO alleges the below assignment to demonstrate standing.

2. On May 3, 2016, **Preferred Medical Plan, Inc.** ("PMPI"), irrevocably assigned all its rights and claims to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees to MSP Recovery, LLC ("PMPI Assignment"). Specifically, the PMPI Assignment states:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recovery monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assignees Claims", as also specified in Section 1.1. The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. The Assignment is intended to encompass and does hereby relate to any irrecoverable assignment in law and/or in equity. The Assignment shall be complete and irrevocable.

3. On August 8, 2016, MSP Recovery, LLC entered into an assignment agreement with MAO-MSO Recovery II LLC, Series PMPI, a segregated series of MSP Recovery Delaware

LLC, whereby it irrevocably assigned its right to recover payments pursuant to state and federal as previously assigned from PMPI. Specifically, Section 1.1 of the agreement states that:

> [a]ssignor hereby irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, all of Assignor's right, title, ownership and interest in and to all Assigned Claims, plus all proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party in connection with the Assigned Claims, and all rights and claims against primary payers and/or third parties that may be liable to Assignor arising from or relating to the Assigned Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".

4. Consideration was given between each party in executing these assignment agreements.

Plaintiff Series 44's Assignment Demonstrating Standing

1. Certain series of Series 44 executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Series 44 through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Series 44 alleges the assignments below to demonstrate standing.

2. Effective April 28, 2016, **Health First Health Plans, Inc. ("HFAP")** irrevocably assigned to MSP Recovery, LLC all rights under the to recover against any liable third party (including Defendants) for payments made on behalf of its Enrollees ("HFAP Assignment"). The HFAP Assignment expressly provides in pertinent part:

> Client hereby irrevocably assigns, transfers, conveys, sets over and delivers to MSP Recovery, and any of its successors and assigns, any and all of Client's right, title, ownership and interest in and to all Claims existing on the date hereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies for Client that Client had, may have had, or has asserted against any party in connection with the Claims and

> all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims, including claims under consumer protection statutes and laws, and all information relating thereto, all of which shall constitute the "Assigned Claims".
>
> …
>
> The transfer, grant, right, or assignment of any and all of Client's right, title, ownership, interest and entitlements in and to the Assigned Claims shall remain the confidential and exclusive property of MSP Recovery or its assigns. This assignment is irrevocable and absolute.

HFAP Assignment at § 4.1.

3. Effective June 12, 2017, MSP Recovery, LLC assigned all rights acquired under the HFAP Assignment to Series 16-05-456, a designated series of MSPRC ("Series 16-05-456 Assignment). The Series 16-05-456 Assignment states:

> [T]he undersigned Assignor … irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee and its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to the Claims and Assigned Claims, (and all proceeds and products thereof, including any related assigned assets and assigned documents) as such terms are defined or contained in that certain (1) Assignment and (2) Addendum to the Recovery Agreement and Assignment Addendum, both given and effective April 28, 2016 and executed on June 1, 2018, by and between Health First Health Plans, Inc., a Florida corporation and Medicare Advantage Organization and party to contract number H1099 with The Centers for Medicare & Medicaid Services, as the "Client" and health plan assignor, and [MSP Recovery], a Florida limited liability company (the "Assignment"); irrespective of when the claims were vested in Client, inclusive of any and all claim(s), causes of actions, proceeds, products and distributions of any kind, and proceeds of proceeds, in respect thereof, whether based in contract, tort, statutory right, and any and all rights (including, but not limited to, subrogation) to pursue and/or recover monies that Assignor had, may have had, or has asserted against any party pursuant to the Assignment from the Client, including claims under consumer protection statutes and laws, any and all rights and claims against primary payers and/or third parties that may be liable to Client arising from or relating to the Claims and all information relating thereto.

Series 16-05-456 Assignment at p. 1.

4. On October 22, 2020, Series 16-05-456 irrevocably assigned all the rights it acquired from MSP Recovery, LLC to Series 44-20-456, a designated series of Series 44 ("Series

44-20-456 Assignment):

> Assignor . . . hereby irrevocably assigns, transfers, conveys, sets over, and delivers to [Series 44-20-456] and its successors and assigns, (i) any and all of Assignor's right, title, ownership, and interest in and to the [claims], as well as (ii) the "Claims" and "Assigned Claims", and all proceeds and products thereof (collectively the "Assigned Claims") as such terms are defined in the Agreements.

Series 44-20-456 Assignment at p. 1.

5. Consideration was given between each in executing the HFAP Assignment, the Series 16-05-456 Assignment, and the Series 44-20-456 Assignment.

Plaintiff Claims PROV's Assignment Demonstrating Standing

1. Certain series of Claims PROV executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims PROV through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims PROV alleges the assignments below to demonstrate standing.

2. On February 3, 2021, **Pura Vida Medical Center, LLC** ("VIDA") irrevocably assigned all its rights and claims to recovery against any liable entity (including defendants) for payments made on behalf of its Enrollees to Series 20-06-1374, a designated series of MSP Recovery Claims PROV, Series LLC. Specifically, the VIDA Assignment, states the following:

> [Assignor] irrevocably assigns, sells, transfers, conveys, sets over and delivers to Assignee, and any of its successors and assigns, any and all of Assignor's right, title, ownership and interest in and to all of Assignor's Claims existing on the date hereof, and rights arising from and related to the claims data transferred to Assignee (or its affiliates or service providers, including MSP Recovery), these Claims encompassing the "Assigned Claims." This assignment is irrevocable and absolute, and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

3. Consideration was given between the parties in executing this assignment.

Plaintiff Claims CAID's Assignment Demonstrating Standing

1. Certain series of Claims CAID executed irrevocable assignments of any and all rights to recover payments made on behalf of their Assignors' Enrollees and health plan members. These assignments authorize the designated series, and in turn Claims CAID through its LLC Operating Agreement, to pursue and enforce all legal rights of recovery and reimbursement for health care services and benefits. Claims CAID alleges the assignments below to demonstrate standing.

2. On February 3, 2021, **Sal Health Group. LLC d/b/a Salubris** ("Salubris") irrevocably assigned all its rights and claims to recovery against any liable entity (including Defendants) for payments made on behalf of its Enrollees to Series 19-10-1128, a designated series of MSP Recovery Claims CAID, Series LLC ("Salubris Assignment"). Specifically, the Salubris Assignment, states the following:

> [Assignor] irrevocably assigns, transfers, conveys, sets over and delivers to Assignee, and any of its designated series, successors and assigns, any and all of Assignor's right, title, ownership, and interest in and to all of Assignor's Claims and rights arising from and related to the claims data transferred to Assignee (or its affiliates or services providers, including MSP Recovery, LLC) for the period encompassing dates of services from June 1, 2014 and continuing up to, including and through June 30, 2020, these Claims encompassing the "Assigned Claims." The assignment of the Assigned Claims set forth herein is irrevocable and absolute and is broad with respect to recovery efforts and is not limited to any particular recovery strategy regarding reimbursement or recovery efforts.

3. Consideration was given between the parties in executing this assignment.